**The BILAG Biologics Prospective Cohort:**

**Long-term Safety of New Treatments in the Management of SLE**

**SUPPLEMENTARY INFORMATION SHEET – LUPUS AND COVID-19**

**Participant Information Sheet (PIS)**

You are being invited to take part in an additional section of the BILAG BR research study to look at lupus and COVID-19. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

**About the research**

Thank you for taking part in the BILAG BR. We would like to ask for your consent to further help us in our research aims. You may wish to read this patient information sheet (PIS) alongside the original PIS you received for the study. If you no longer have a copy of this, please contact the research team and they will email or post you a copy.

* **What is the purpose of the additional section to the research?**

The results from this additional section will be used to help rheumatology doctors advise individuals with SLE on medications, COVID-19 vaccinations and infection risk. The BILAG-BR was started to study the long-term safety of new treatments for systemic lupus erythematosus (SLE) and the emergence of COVID-19 means it is an important resource for us to learn about how COVID-19 affects people with this condition. We know that many treatments for SLE suppress the immune system but we do not understand the effects these have on risk of COVID-19 and how well COVID-19 vaccines work in SLE because it is a new infection and SLE is rare condition.

The additional section to the research involves three parts:

1. A questionnaire, to understand individual behaviours and their potential impact on infection risk.
2. A dried blood spot test (see below for more information on what this is). To tell us what proportion of patients have some immune response to the virus, from previous infection or vaccination.
3. Blood tests to look in detail at how immune cells in people with SLE respond after SLE vaccination.

* **Will the outcomes of the research be published?**

We may publish this research in academic books and journals, on our study website (<https://sites.manchester.ac.uk/bilag/our-discoveries/>) and through charities such as LUPUS UK. If we do this, any information about you will be anonymised. We may also share anonymised information about your blood sample with other collaborators (academic institutions or commercial organisations worldwide) to perform research that will lead to a greater understanding of the COVID-19 pandemic and lupus.

* **Who has reviewed the research project?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by North West – Greater Manchester (GM) West Research Ethics Committee (reference 09/H1014/64).

* **Who is funding the research project?**

The BILAG BR has been funded by a number of unrestricted educational grants, including those from the charity LUPUSUK and the pharmaceutical companies, Roche and GlaxoSmithKline

**What would my involvement be?**

* **What would I be asked to do if I took part?**

We are writing to you to ask for your consent to do any, some or all of the following:

1. **Complete an online, paper or telephone survey about your experience of the COVID-19 pandemic.**
2. **Provide a dried blood spot sample.**
3. **Provide blood samples before and/or after you have the COVID-19 vaccination.**

If you agree to give a blood sample, we ask you to gift your blood samples for research.

1. **The COVID-19 Survey**

With your permission, we will ask you to complete a survey about lupus and COVID-19. This can be completed online, using a mobile device or computer, by post, or over the phone. You will not need to enter any personal information online. You will be identified by your BILAG BR study number, your month and year of birth.

**How to complete online**

If you would like to complete the survey online, please enter the following address into your browser:

<https://www.aruk.manchester.ac.uk/BBR/>

You will need to enter your unique 5-digit study ID number (found on the front of this leaflet). If you don’t have your study ID, your hospital care team should be able to provide it, or you can email the study team (contact details below).

Next:

* 1. Enter your unique **5-digit** study ID and your month and year of birth
  2. Confirm your consent for each relevant part of the study by ticking the boxes
  3. Confirm your consent by clicking “consent”

You will then be taken to the online lupus and COVID-19 survey. This should take approx. 10-15 minutes to complete.

**How to complete the survey by post**

If you would prefer to take part in the survey by post, you can complete the enclosed paper survey and return it in the pre-paid addressed envelope provided. Please ensure you complete the first page of the survey, initialling the boxes where necessary, to provide your consent to participate in the survey, and let us know whether you would also like to be involved in the other aspects of the study.

**How to complete the survey over the telephone**

Alternatively, you can complete the survey over the telephone. Please return the enclosed consent form in the envelope provided and call the researcher, Dr Mia Rodziewicz 07825963249 to complete the survey. If we are unable to answer your call, please leave a message including your telephone number and a suitable time to call you back. Dr Rodziewicz will take you through the online survey, entering your responses on your behalf.

1. **Dried blood spot test**

*What is a dried blood spot test?*

A blood spot test involves using a small device to make a pin prick on the tip of one of your fingers and collecting some drops of blood (about 7), onto a card. This can be done by yourself at home. There is a minimal risk of causing discomfort and very minor bruising. Should you agree to the test, you will be provided with detailed instructions on how to do the pinprick and collect the drops of blood? If you consent to provide us with a dried blood spot, by either ticking the relevant box on the online consent form or speaking to the researcher, we will send the pack to your address and it can be posted back to the laboratories at University of Manchester in the packaging provided.

1. **Blood samples after COVID-19 vaccination**

If you consent to provide us with blood samples after your COVID-19 vaccination, this will be collected by your usual clinic team, at the time of a routine appointment, and posted back to the laboratories at the University of Manchester for analysis. There are minimal risks associated with having blood taken and include discomfort and minor bruising.

It is possible that our tests may show a complete lack of immunity to COVID-19 in some individuals. In such a case, this would be communicated to your usual rheumatology team who would contact you to discuss the finding.

* **What will happen to the research samples?**

Samples and data will be pseudo-anonymised (linked to a donor number with limited information, but not identifiable) so that no-one receiving or processing the samples and data will know they belong to you. All samples will processed and analysed at the University of Manchester. They will be stored in a laboratory at the Versus Arthritis Centre for Epidemiology at the University of Manchester. This study may involve DNA analysis but the results will not have implications for your relatives. The research samples may also be analysed by academic, NHS, and commercial organisations in the UK. After the study ends, we may wish to use your anonymised data and samples in future ethically approved research.

* **Will I be compensated for taking part?**

There is no payment available for patients taking part in the study.

* **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. Your participation in any, some or all three steps is entirely voluntary, so you don’t have to take part if you do not want to – you can refuse permission for this and still take part in the rest of the BILAG BR study. You are free to withdraw at any time without giving any reason; this will not affect your medical care or your legal rights.

Please ask a member of the research team if there is anything that is not clear, or you would like more information.

If you do decide to take part you will be given this information sheet to keep and will be asked to consent to take part by either returning the paper copy of the consent form, signing into the link and electronically confirming your consent, or by speaking to Dr Rodziewicz over the phone.

If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

**Data Protection and Confidentiality**

* **What information will you collect about me?**

In order to participate in this section of the research project we will not need to collect any further information that could identify you, called “personal identifiable information”. For this section, we will on need your unique study ID, your month of birth and your year of birth entering into the online system.

* **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law, which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

* **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095), which can be found at the following link:

<http://documents.manchester.ac.uk/display.aspx?DocID=37095>

* **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

We will not collect any information from which you can be identified for this part of the research. We will use your unique study ID, along with your month and year of birth to confirm your details. The website used to collect data for this study is GDPR compliant – it does not own or access the data you enter. Your survey responses will be downloaded and stored on a secure server run by the University of Manchester to which only members of the research team will have access.

With your consent your anonymous information may be shared in order to support additional research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/). (Policy available at <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>). Any information shared with other researchers will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research in lupus, and cannot be used to contact you regarding any other matter.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

**What if I have a complaint?**

If you have a complaint that you wish to direct to members of the research team, please contact:

**Professor Ian Bruce Versus Arthritis Centre for Epidemiology, Faculty of Biology, Medicine and Health, Stopford Building, The University of Manchester, Oxford Road Manchester M13 9PT Tel: 0161 276 7936, Fax: 0161 276 8690 Email: benjamin.parker@manchester.ac.uk**

**If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact**

TheResearch Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk)  or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information. Tel 0303 123 1113 or online via <https://ico.org.uk/make-a-complaint/>

**Contact Details**

If you have any queries about the study or if you are interested in taking part then please contact:

**The researcher:** **Dr Mia Rodziewicz**

**Division of Musculoskeletal & Dermatological Sciences,**

**Faculty of Biology, Medicine & Health,**

**Stopford Building, The University of Manchester**

**Oxford Road, Manchester**

**M13 9PT**

**Tel. 0161 2751614**

**Email** [**Mia.rodziewicz@manchester.ac.uk**](mailto:Mia.rodziewicz@manchester.ac.uk)

**The Study Coordinator:** [**Emily.sutton@manchester.ac.uk**](mailto:Emily.sutton@manchester.ac.uk)

**The Project Administrator:** [**Alison.fountain@manchester.ac.uk**](mailto:Alison.fountain@manchester.ac.uk)