Title of Project: Are new treatments for rheumatoid arthritis harmful to long term health? (British Society for Rheumatology Biologics Register for Rheumatoid Arthritis, BSRBR-RA)

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PARTICIPANT INFORMATION SHEET

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How to contact us

If you have any questions about this study or research in general please contact us at:

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You are invited to take part in a research study

- The "**British Society for Rheumatology Biologics Register for Rheumatoid Arthritis**" or "**BSRBR-RA**" is a study to help researchers understand whether new treatments for rheumatoid arthritis are harmful to long term health.
- Before you decide whether to take part, 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 and ask for anything that is unclear to be explained.
- If you would like more information, please email the BSRBR-RA team at The University of Manchester or talk to your rheumatology team at the hospital. More information about the BSRBR-RA is also available at **www.bsrbr.org**.
- Thank you for taking the time to consider participating in the BSRBR-RA.

Important things that you need to know

- Biologic drugs have been available for the treatment of rheumatoid arthritis in the UK for the past two decades with new drugs being approved each year.
- All of these drugs have been through rigorous clinical trial testing to make sure they are safe and effective in the short-term.
- This research study has been designed to collect data on these drugs in routine NHS rheumatology clinics to make sure these drugs are safe and effective in the longer term.

What is the purpose of the study?

The purpose of this research is to assess whether some of the biological and other new therapies (for example: *Amgevita, Benepali, Cimzia, Enbrel, Erelzi, Flixabi, Jyseleca, Humira, Inflectra, Kevzara, Olumiant, Remsima, Rixathon, RoActemra and Xeljanz*; please visit our website to see a list of drugs we are interested in at www.bsrbr.org) used in the treatment of rheumatoid arthritis have a greater risk of serious side effects and long-term health problems than established treatments such as methotrexate. As rheumatoid arthritis requires lifelong treatment, it is important to understand how the newer drugs compare to other treatment options in terms of side effects when used for a period of many years.

All of these drugs have been tested in clinical trials and approved for use but more information is needed. The reasons for this are (i) clinical trials run for a short period of time (weeks/months), (ii) have fewer numbers of participants compared to those who will ultimately be treated with the drug in the NHS and (iii) may exclude participants with additional diseases (comorbidities). Therefore, we especially need more information on the side effects of these drugs prescribed in NHS rheumatology clinics over a long period. The study therefore involves following up patients who are taking a number of different drugs for rheumatoid arthritis. The study team will observe the frequency with which long-term side effects occur in patients receiving the newer treatments compared to those taking established treatments. This will provide patients and doctors a better picture of any increased risk of side effects for the newer drugs.

The study is funded by the British Society for Rheumatology (BSR). This is the professional clinical society of adult and paediatric rheumatologists, specialist nurses and other allied health professionals, which supports its members to deliver the best possible care for people living with rheumatic diseases. The BSR receive funds from a number of pharmaceutical companies who manufacture these therapies to support this study and has chosen The University of Manchester to carry out this independent research.

Why have I been chosen?

You have been chosen to participate as you have either been started on (i) one of the "biological" or other new treatments, or you have been started on (ii) one of the established treatments and can provide useful comparison information. By participating, you will help us build up the amount of data for analysis.

Do I have to take part?

You do not have to take part. If you do decide to take part, you can keep this sheet and will be asked to sign the consent form. Your participation will not interfere with the standard of care you receive.

What are the risks of taking part?

The study will run alongside your routine clinical care at the hospital. It will not influence this process at all. Therefore, there are no foreseeable risks associated with participating in this study.

What are the benefits of taking part?

Although there is no clinical benefit gained by participation in the study, the information obtained from this study may result in changes in future treatment of patients with rheumatoid arthritis and will help patients and doctors make more informed treatment decisions.

Why do you need my written consent?

Your participation in the BSRBR-RA is entirely voluntary. By signing the consent form, you would be confirming your willingness to take part.

What will happen to me if I take part?

Your participation will involve the following:

(i) Agreement to complete the questionnaires and other survey forms about your health. You may find some of the questions to be of a sensitive or personal nature. You are not obliged to answer all questions. You will be contacted at least annually to ask you to complete the BSRBR-RA follow-up questionnaires.

(ii) Agreement with your specialist to provide information of relevance to the study (including treatments and illnesses you have) from your NHS hospital medical records to the study researchers. Copies of the data collection questionnaires are available at: www.bsrbr.org.

(iii) Agreement for your date of birth, gender and NHS/CHI/HCN number to be shared with other UK national healthcare databases (including NHS England and the Department of Health and Social Care (DHSC) but please see www.bsrbr.org for a full list) for the purposes of matching identifiable information already held by these national databases. There are different databases for each of the devolved nations in the UK. This will allow these national organisations to provide the study team with additional clinical information held on their NHS files about your hospital admissions or details if you are registered as having cancer or in the event of your death. By this means, events such as an admission to hospital (that may not have been reported by the rheumatology team) will be collected. This will result in a more complete picture of your health experience and will enable the study to provide more accurate results on the long-term safety of the biologic drugs. You can choose to opt-out of this aspect of the study either at the point of consent or at any point during participation by notifying the study team directly.

At this stage we do not know how long we will want to collect this information from you and about you. It is likely to be for at least five years because we are interested in the long term effects of these drugs (some patients have been in the study for up to 20 years so far). It is likely that, subject to funding, this long-term observational study may continue for many years to come. Research data will be stored for 15 years following study end and subsequently securely destroyed. We would also ask for your agreement to be contacted about other studies or a follow-up of this study through your doctors.

Will the research influence the treatment I receive?

The research does not alter the treatment you receive. Your specialist will start and stop treatments as determined by your clinical condition.

How will my data be processed?

Information will be updated at least annually from you and your rheumatology team and collected via computer systems. Data will be sent using a secure network. Your identifiable information will be held in a secure format by the research team (named by the study's Chief Investigator) at The University of Manchester and trusted third parties where appropriate legal agreements are in place (see next section).

How will you keep my data secure?

The University of Manchester and The British Society for Rheumatology are data controllers for the research and are responsible for the purpose and manner in which your data are processed. They will ensure that your data are processed fairly and lawfully in accordance with the General Data Protection Regulation (GDPR).

Your personal data will not be shared with other parties beyond the study data controllers, providers of healthcare data and approved data processors (any person or organisation that processes your data on behalf of the data controllers) where appropriate contractual agreements are in place with the data controllers.

The BSRBR-RA, located at The University of Manchester, has put a number of rigorous procedures in place to protect your personal data and keep it secure:

- We implement computer security to block unauthorised access to the computers/systems that hold personal information.

- Personal identifiable data will be held in an encrypted format at the University of Manchester. Encryption allows information to be stored in an unreadable manner making it accessible to the research team (named by the study's Chief Investigator) only with the use of a University of Manchester username and password.

- Any access to personal information will be restricted within the BSRBR-RA team via a University of Manchester username and password. This information is stored for two purposes only (i) to send study forms about your health to you, and (ii) for the purpose of linking to information already stored by national providers of healthcare data, e.g. NHS England and the Department of Health and Social Care in England. Your identifiable data will not be shared with any other parties beyond this. All BSRBR-RA staff will sign annual confidentiality agreements as part of their employment contracts.

- If your data is provided as part of a larger dataset to bona-fide researchers (who have had their research question approved by the BSR) outside of the BSRBR-RA team, information that could identify you will not be provided or shared.

Will any other third parties have access to my data?

A number of pharmaceutical companies who manufacture these therapies will have access to some study data for further safety monitoring but this will not include directly identifiable information such as name or NHS or CHI number in Scotland. It will include your initials, gender and month and year of birth. This is for the purpose of updating records with the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the US Food and Drug Administration (FDA). As the pharmaceutical companies are international, there is a possibility that medical information may be sent outside of the UK and outside of the European Union for analysis. By signing the consent form you are agreeing to this transfer.

The pharmaceutical companies will act as data controllers for this information accessed from the study for safety and regulatory reporting purposes only. Appropriate legal agreements will be put in place between the data controller/s and all data processors further ensuring the safety of your data.

Your medical records will state that you are in this study. By signing the consent form, you are allowing the rheumatology team to permit the University of Manchester or approved data processors to have access to information from your medical records relevant to the study for the purposes of capturing the data.

In certain circumstances your medical records or study data may be looked at by a government drug regulatory agency or by authorised members of The University of Manchester, their representatives/agents and individuals from the hospital. This is for the purpose of checking that the data is correct or checking that the study is being carried out properly.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with data protection law which protects 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". For more information about this, please view the BSRBR-RA website (https://www.bsrbr.org/for-participants/protecting-your-information/) to view the University of Manchester Privacy Notice for Research

(hard copies of the University of Manchester Privacy Notice for Research are also available upon request).

How do I withdraw from the study if I want to?

Potential participants are asked to discuss any concerns they might have with their rheumatology team or the BSRBR-RA team in the first instance.

You can withdraw at any time from the study after giving your signed consent, by contacting the BSRBR-RA staff (phone, letter, email). This will have no effect on the standard of medical care you receive. We can then discuss the desired level of withdrawal from the following three options:

Option 1: No further participant contact:
We would not request you complete any further questionnaires or surveys about your health, but we would continue to receive information from your rheumatology team at the hospital and via the linkage with the national databases.

Option 2: No further participant or hospital contact:
We would not request you, or the rheumatology team at the hospital, complete any further forms or surveys asking about your health. Your record would still be linked with the national databases.

Option 3: Complete withdrawal:
We would not request completion of any further surveys or forms, either from yourself, or your rheumatology team at the hospital. We would also contact the national databases to un-link your record so no further information was received on your health status from the time you withdrew.

What will happen to the results of the study?

The results of the study will be presented at scientific meetings and published in medical journals. We will also post the results in lay terms on the BSRBR-RA website for you to see: www.bsrbr.org. No identifying information will be used in these analyses. A full list of our publications (60+ to date) using data collected in this study can be found on the above website. Results of the study will also be sent to you and your rheumatology team via study newsletters.

Who is organising the study?

The study is being co-ordinated and sponsored by the University of Manchester and the lead researchers, Professor Kimme Hyrich or Dr Kath Watson can be contacted for further details **(**Email: biologics.register@manchester.ac.uk). (Contact Name: _____Tel: _____ Email: _____) whom you should contact for further information or if you have any concerns.

Who has reviewed the study?

Before any research study can go ahead, it has to be checked by a research ethics committee and the Health Research Authority (HRA) to make sure that the research is fair and transparent. The study has been reviewed and approved by the North West 7 REC GM Central Research Ethics Committee (MREC 00/8/053 (IRAS: 64202)). If you have any concerns about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

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 The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: 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 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) Tel 0303 123 1113

If you do decide to participate in this study, please complete the consent form which you have been given and hand it back to your Consultant/Research Nurse.