
# CONSENT FORM

(Version 11.0; dated 22/11/2023)

**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)

**Name of Researcher:** Professor Kimme Hyrich

Please initial or tick boxes

1. I confirm that I have read and understand the information sheet (version11.0; dated 22/11/2023) for the above study and have had the chance to ask questions.
2. I agree to participate in the study.
3. I agree to complete survey questionnaires about my health *(optional).*
4. I understand that my rheumatologist Dr\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ may provide the researchers with information from my NHS medical records that is relevant to the study.
5. I am aware that I can request to stop completing questionnaires directly at any time and
still continue to be registered with the study via my rheumatologist.
6. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
7. If I do decide to withdraw from the study, I understand that any identifiable data that has already been collected will be retained and used in the study.
8. I understand that my personal data will not be shared with other parties beyond the data controllers and approved data processors where appropriate legal agreements are in place. I give permission for these individuals to have access to data from my NHS medical records relevant to this study for the purposes of this study only.
9. I understand that some of my data may be transferred to pharmaceutical companies outside of the UK and the European Union. This will not include directly identifiable data, but will contain my initials, month and year of birth, and gender.
10. I also understand that under some circumstances, my medical records may be looked at by a government drug regulatory agency (for instance, the Medicines and Healthcare products Regulatory Agency (MHRA)) or by authorised members of the University of Manchester, their representatives/agents and individuals from the hospital for checking the study is being carried out properly. I give permission for these individuals to have access to my records.
11. I understand that my date of birth, gender and NHS/CHI/HCN will be shared with other national NHS databases (including NHS England and the Department of Health and Social Care (DHSC)); see the full list on [www.bsrbr.org](http://www.bsrbr.org)) for the purposes of matching identifiable information already held to provide additional data on my health *(optional)*.

1. I agree to information from which I can be identified being held by the University of Manchester as the study sponsor as well as other approved data processors where legal agreements are in place for the purpose of processing the data for the study only.
2. I agree to my de-identified information recorded in the BSRBR-RA database to be used
for research purposes.
3. I agree to allow the researcher to make contact with me about other studies or a follow-up of this study through my rheumatology team at the hospital *(optional)*.

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| --- | --- | --- | --- |
|  | NAME | SIGNATURE  | DATE |
| PARTICIPANT |  |  |  |
| PERSON TAKING CONSENT |  |  |  |
| RESEARCHER (if different) |  |  |  |

*NB: A copy for the patient, the researcher and one for the hospital notes.*