Unique ID number:

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Patient Information Sheet and Consent Form **PERSONAL COPY**
(Please retain for your records)

Study Title: The British Society for Rheumatology Biologics Registers – Ankylosing Spondylitis (BSRBR-AS)

We would like to invite you to take part in the above research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. ***If you have any questions, please ask the research nurse or contact the study team on 01224 437141 or at bsrbr-as@abdn.ac.uk***

What is the purpose of the study?
The BSRBR-AS has been set up to monitor the safety of treatments for Ankylosing Spondylitis(AS) patients and to find out more about how treatments affect the lives of AS patients in areas like work, driving and general quality of life.

Who is organising and funding the research?
The British Society of Rheumatology has commissioned researchers at the University of Aberdeen to co-ordinate the BSRBR-AS. This is being done by the Epidemiology Unit and the lead researchers are Professor Gary Macfarlane and Dr Gareth Jones, who can be contacted for further information. Parts of the study are also being managed by the Robertson Centre for Biostatistics at the University of Glasgow.

A number of rheumatology departments around the UK are taking part in the BSRBR-AS by asking their eligible AS patients to join the study. We aim to recruit over 2000 patients. Your consultant has determined that you are eligible to join the study.

Do I have to take part?
It is up to you to decide to join the study. We will describe the study in this information sheet. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?
If you decide to take part you will continue to be treated as usual by your rheumatology team.

What will I have to do?
The study needs your permission to gather data from your medical notes and from future clinic visits. This is all data that your care team will be collecting whether or not you decide to join the study. We would also like permission to link your data to national databases including the National Health Service Information Centre, and other appropriate NHS systems so we can find out about any important events such as stays in hospital. Neither of these need you to do anything else, they will happen automatically, but we do require your consent. Also, we will ask you to complete follow-up questionnaires about once a year about your disease and to keep a record of any time you spend in hospital. We may also send you questionnaires if your treatment changes or your partner becomes pregnant.

If we don't hear back from you after we've sent you a regular follow-up questionnaire, we will send you a reminder. If you don't wish to receive a reminder – or even if you wish to withdraw from the study altogether – you can contact the researchers at the University of Aberdeen on 01224 437141 or via bsrbr-as@abdn.ac.uk. These details will be printed on all questionnaires that you receive from us.

The BSRBR-AS is running until at least December 2017.

What if I am already in SIRAS?
There is already a large study of AS underway in Scotland and Northern Ireland – the **S**cotland and **I**reland **R**egistry for **A**nkylosing **S**pondylitis (SIRAS). If you live in Scotland or Northern Ireland you may have already been approached to participate in this study. If you are currently participating in SIRAS, the BSRBR-AS will now take over, and you will only be asked to complete questionnaires for one study (the BSRBR-AS).

What are the possible disadvantages and risks of taking part?
You will not be disadvantaged in any way by joining the study. Your care team will continue to care for you as usual. There are no insurance implications.

What are the possible benefits of taking part?
Nothing about the way your rheumatology care team treats you will change as a result of taking part in the study. We hope that the information we get from this study will help improve the treatment of people with AS and related conditions.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. They can be contacted at the University of Aberdeen on 01224 437141 or via bsrbr-as@abdn.ac.uk.

If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from http://www.nhsnss.org/pages/contact/feedback.php for Scotland and http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx for England.

Will my taking part in the study be kept confidential?
Yes. All study materials will identify you using only a unique ID number. Your name and contact details will be stored separately from all other study materials and all data storage (both paper and electronic) will be kept secure at all times – only study personnel will have routine access to your data. We will follow Good Clinical Practice in determining who has access to data.

It is important that we can keep in contact with you for the remainder of the study, even if you change address. You will be asked to provide contact details for two people (friends or relatives) who we may contact, but only in the event that we lose contact with you. These details will form part of your study record and will be treated with the same confidentiality as all other data. However, we ask that you please check to make sure that these people are happy for you to provide their contact details to us.

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What will happen to the results of the research study?
Results from the study will be publicised in academic conferences and journals. They will also be reported to the rheumatology centres taking part.
You will receive newsletters summarising the findings of the research, but it may be some time before these are available.

Who has reviewed the study?

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 by the North East – County Durham and Tees Valley Research Ethics Committee.

Consent

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. Initials.....
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Aberdeen, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. Initials.....
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I understand that the study questionnaire collects information about my health which might not have been collected previously by the rheumatology clinic staff, and that my consultant may be interested in seeing my responses to various questions. I give permission for the rheumatology clinic staff to have access to my questionnaire responses. *Initials.....*
I give permission to the BSRBR-AS study group to contact me regarding future studies *Initials.....*
I agree to take part in the above study. *Initials.....*

Will any genetic tests be done?

Separate to the BSRBR-AS, but linked to it, we are conducting a study to examine genetic influences of AS. Accordingly, we would like to invite you to donate a saliva sample for genetic analysis. This part of the study is optional, and you can still take part in the main study if you opt out of the genetic sub-study.

Research has already identified several genes that have given us a much clearer understanding of the processes by which AS develops. However, many of the genes are still unknown. Our goal is to identify as many of these genes as possible so that we can understand the disease better and develop better ways of diagnosing and treating it. Any sample you provide will only be used in this type of research and will not be tested for any other diseases.

If you choose to donate a sample you will be sent a saliva sample donating kit through the post containing full instructions and additional information as well as a reply-paid envelope for you to return your sample to the co-ordinating centre. You can donate a saliva sample even if you have previously given a sample to another study.

There are no risks or side effects to giving the optional saliva sample in this study. We are not testing for any specific diseases, we are looking for differences in DNA (genes) between people with AS and people without AS.

I understand that my participation in this (genetic) part of the current study is voluntary and does not affect my participation in other parts of the study. Please send me further information and a saliva sample donation kit. Initials.....

.....	.....	.....
Name of Patient	Date	Signature
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Further information and contact details: Co-ordinating Centre Email: bsrbr-as@abdn.ac.uk Telephone: 01224 437141	Epidemiology Group Institute of Applied Health Sciences, University of Aberdeen, School of Medicine and Dentistry, Polwarth Building, Foresterhill, Aberdeen, AB25 2ZD,

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