British Society for Rheumatology

Psoriatic Arthritis Register

UNIVERSITY OF ABERDEEN

British Society for Rheumatology Psoriatic Arthritis Register (BSR-PsA)

PARTICIPANT INFORMATION SHEET (BIOBANK)

As part of your participation in the above study, we would also like to invite you to take part in the BSR-PsA biobank. This part of the study is an optional add-on.

This leaflet provides extra information specifically about the biobank. It doesn't seek to undo any of the information in the main study Participant Information Sheet. It explains what the biobank is, and what is involved, to help you decide.

Please read the following information carefully and discuss it with others such as family members or your GP if you wish. Please contact us if there is anything that is not clear or if you would like more information – our contact details are on the back of this Participant Information Sheet.

Please take as much time as you like to decide.

1. What is the purpose of the biobank?

Some of the hospitals involved in the BSR-PsA are asking their patients to donate some blood and urine samples. These will be stored for future analysis to provide researchers with a detailed picture of the biological reasons why different patients respond differently to the same drug. This research will hopefully lead to PsA being treated more effectively in the future.

2. Why have I been invited?

You are a participant in the BSR-PsA and your hospital is one of those involved in setting up the biobank.

3. Do I have to take part?

No, taking part in the biobank is completely voluntary. You can remain part of the main BSR-PsA study even if you choose not to participate in the biobank.

4. What will happen if I decide to take part?

You will be asked to donate a blood sample, plus a urine sample, when starting a new treatment, and three months later. Each time your doctor recommends a major change in treatment – for example, stopping one medicine, and starting another – you may be asked to donate new samples, and again after three months.

Your samples will be collected during your routine clinic visits so shouldn't require any additional hospital visits. After you have given your blood and urine samples, you will not be required to do anything else for the biobank, although any results will be linked to the clinical data, and data that you've already provided, as part of the main BSR-PsA study.

5. How will my samples be used?

Your samples will be prepared in your local hospital, and then transported to the biobank facility at the NHS Grampian Biorepository. There they will remain frozen until they are analysed.

The samples may be analysed in several ways. This may involve Investigating various molecules ("biomarkers") associated with PsA, including DNA and RNA (genetic) molecules.

6. How long will my samples be stored?

Investigating the biological reasons why individuals can respond differently to the same treatments can take a long time. During this period, new research techniques may be developed to analyse your samples more effectively. Therefore, samples will be stored for up to 10 years.

7. What if I change my mind and want to withdraw?

You can choose to withdraw at any time and have the right to ask for any of your samples stored in the biobank to be withdrawn and destroyed. You do not have to give a reason for your withdrawal. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

8. What are the possible disadvantages of taking part?

As with all routine blood tests / samples, you may develop some minor bruising or infection at the site where the blood was taken. Staff who have been trained in this procedure will take the samples and take the appropriate action if any of these things were to occur.

Any information obtained about samples during analysis is for research purposes only. You will not be informed of any of the results of the tests. These samples are separate from any which your doctor deems necessary to help treat your disease. You will not benefit financially if any information obtained from your samples is used to develop new treatments or tests for PsA.

9. What are the possible advantages of taking part?

You would be helping to increase what we know about PsA, and how best to treat it. However, there will not necessarily be any personal benefit to you taking part.

10. What if something goes wrong?

If you have any concerns with any aspect of this study please ask to speak to the researchers who will do their best to answer your questions – contact details are on the back of this Participant Information Sheet, and will be printed on all questionnaires you receive from us.

If you remain unhappy and wish to make a formal complaint, you can do this through the NHS complaints procedure. Further information about this can be obtained from:

- England: www.nhs.uk/nhsengland/complaints-and-feedback/pages/nhs-complaints.aspx
- Scotland: https://nhsnss.org/contact-us
- Wales: www.wales.nhs.uk/ourservices/contactus/nhscomplaints

11. Will my data and samples be kept confidential?

Any identifying information such as your name and date of birth will be removed from your blood and urine samples. They will be given a unique identifying barcode making them anonymous during their processing, storage and analysis, but enabling them to be linked to your study ID number.

Only members of the coordinating team will have access to the encrypted information, linking your biobank sample barcodes to your study data, which will be kept confidential and password protected. Relevant legislation will be followed in determining which individuals can access this.

As part of the collaborative nature of modern health research, your samples may be analysed by researchers who work in the NHS, in universities, other research institutions or in biotechnology or pharmaceutical companies. However, persons analysing your samples will not have access to any personal identifying information and your samples will be identifiable only by barcode.

The study is overseen by the British Society for Rheumatology. The society has a Data Access Committee that will decide whether any intended research is justified, and all scientists will sign a contract that covers how samples may be stored and analysed. This contract applies even on the event that your samples are transferred abroad.

As with the main study data, no-one analysing the data will have access to your name and contact details and it is important to note that you will not be identifiable in any publications and your personal data will not be handed on to any external parties – in accordance with Data Protection legislation.

12. Who has reviewed the study?

All research involving the NHS is reviewed by independent group of people, a Research Ethics Committee, to protect your interests. This study has been reviewed by the West of Scotland Research Ethics Committee 3.

For further information, or if you have any questions, please contact Dr Karen Forrest Keenan, the study coordinator:

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The NHS Health Research Authority offer independent and impartial advice on whether or not to take part in clinical research, see: www.hra.nhs.uk/about-us/what-we-do/taking-part-or-getting-involved-research.

Alternatively, if you would like to speak to another health professional who is not directly involved in the study, please contact:

Ann Tierney
Centre for Rheumatic Diseases, Ward 15, Royal Infirmary
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Email: ann.tierney@ggc.scot.nhs.uk
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Thank you for taking the time to read this Participant Information Sheet.

Please keep it for future reference.