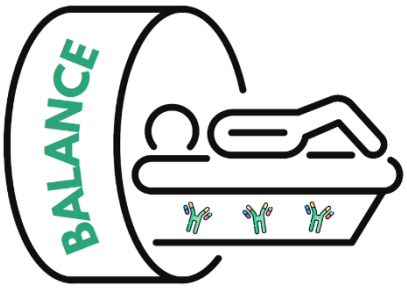
Insert local contact details e.g. TRUST LOGO (once approval is in place)

*Add contact details of the local research team and either the Local Investigator*

**PARTICIPANT INFORMATION SHEET**




# BALANCE- **B**imekizumab **A**nd **L**iver infl**A**mmation in psoriatic disease: a pio**N**eering **C**linical inv**E**stigation

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. The pictures on the next page illustrate how the study works. If there is anything that is not clear, or if you would like more information, please ask us, our contact details are above and on the last page.

## Purpose of the study

A previous study, led by our team, found that liver disease can be quite common in individuals with psoriasis and psoriatic arthritis (PsA) (often called psoriatic disease) due in part to some of the medications that are used to try to treat it. Also, it appears that those with psoriatic disease seem to have a much higher risk of developing a type of liver disease called non-alcoholic fatty liver disease which also has another name of metabolic dysfunction-associated steatotic liver disease. This can have a big impact on their general health and quality of life. It can also make treating psoriatic disease more complicated because some medicines can make liver problems worse. The doctors and scientists running the BALANCE study have also discovered that some of the newer treatments for psoriatic disease such as Bimekizumab may actually help improve liver health.

There is now available, a new type of MRI scan which can be used to show any inflammation and scarring in the liver and some of other organs – this requires no surgery or any needles. The BALANCE team are now looking for 30 individuals who are about to start Bimekizumab to see if they can use the new type of MRI scan to look at their liver before starting the drug and about 6 months later, and find out how Bimekizumab works in their bodies. The study will also look at images of their heart, lungs, kidneys, pancreas and spleen taken during the same MRI scans – but the main focus will be looking at the images of their liver that are taken during 2 MRI scans. Individuals will also be asked about their psoriatic disease symptoms.

## Overview of the BALANCE study in pictures

Created by Brickclay
from Noun Project

Bimekizumab is a medication currently prescribed to patients with psoriatic disease (psoriasis or psoriatic arthritis (PsA)). If you have the diagnosis of psoriatic disease, and you and your doctor has agreed that you will start on Bimekizumab, you will be approached by your study doctor and/ or nurse (the local study team) to discuss participating in the BALANCE study and answer any questions you might have.

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from Noun Project

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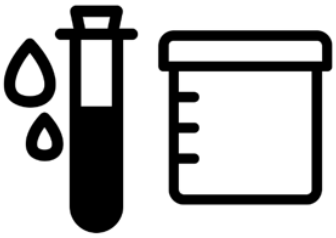
from Noun Project

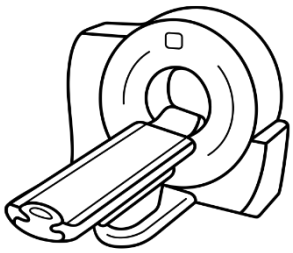
If you agree to take part in the study, you will undergo examination of your skin and/or joints, answer some questionnaires and have blood and stool samples collected for the study. You will also have your first MRI scan.

After 24 weeks of Bimekizumab treatment, you will be invited to repeat the same examinations, questionnaires, sample collections, and MRI scan.



Created by Danishicon
from Noun Project

Created by Travis Avery
from Noun Project



Created by Oleksandr Panasovskyi
from Noun Project

To help you decide if you would like to take part in the BALANCE study, you would need to consent to take part in the study. Sometimes patients are not sure what consent is and if it's safe to take part in a study – the two QR codes on the right link to short videos which can explain these things if you are unsure.

The short videos can alternatively be accessed by going to the links:
*https://vimeo.com/1136166436/ecff80c7c1* and
*https://vimeo.com/1136166734/5f2b6ab90f*

*Anonymous usage statistics on the animated explainer videos referenced within this document are collected by the Oxford Clinical Trials Research Unit at the University of Oxford as part of an implementation project. Further details about what data is collected can be found here https://explain.octru.ox.ac.uk/privacy.html*

**Video "What is consent?"**

**Video "Is it safe to take part in a study?"**

## Why have I been invited?

You have been invited to take part in this study because you have the diagnosis of psoriasis or psoriatic arthritis, and you are over the age of 18. As part of your routine standard care, your doctor has asked you to start a medication called Bimekizumab to treat your psoriasis or psoriatic arthritis. We would like to see whether this treatment has any effect on your liver and other organs, using an MRI scan to look for any changes before and after starting Bimekizumab.


We need 30 patients with psoriasis or psoriatic arthritis to agree to take part in this study.

## Do I have to take part?

No. Taking part in this study is entirely voluntary. The local study team will explain everything to you and you will have time to consider whether you wish to take part and ask as many questions as you would like to.

To take part, you will be asked to sign a consent form. Even after you have signed the consent form agreeing to take part in the study, you can change your mind at any time and without giving a reason. Deciding to take part in/withdrawing from the study will not affect the clinical care you currently receive or will receive in the future or your legal rights.

## What will happen to me if I decide to take part?

The study involves **up to four in-person visits**:

- **Two are clinic visits**. Where possible these will be conducted at the same time as your routine clinic appointments. One visit is conducted before you begin Bimekizumab treatment and one is conducted 24 weeks (~6 months) after starting Bimekizumab treatment.
- **Two visits are for an MRI scan**. Depending on MRI availability at each hospital, the scan may take place at the same time as the clinic visit or may be a separate visit. One scan is conducted before you begin Bimekizumab treatment and one is conducted 24 weeks after starting Bimekizumab treatment.

Within the NHS it is usual practice for patients to begin their Bimekizumab treatment 3-6 weeks after their initial clinic visit. The follow-up clinic and MRI visits will be conducted approximately 24 weeks after your first dose of Bimekizumab. To allow flexibility, the 24-week study visit can be conducted up to 2 weeks before or after it is due, therefore the 24-week study visit could be scheduled between 22-26 weeks after your first dose of Bimekizumab. Therefore, the total length of time you will be involved in the study could vary between 25 to 32 weeks. We expect most participants to be in the study for approximately 28 weeks (6.5 months).

The study visits schedule on the next page shows when the visits are and what will happen at each one.

| Visit details | What will happen? |
|---|---|
| **Visit 1: Screening**<br>**Hospital visit**<br>At routine clinic appointment where possible OR separate research visit<br>***Up to 1 hour*** | • Eligibility assessment by the study team<br>• Consent to take part discussion and signing if you wish to participate<br>• Height, weight, waist & hip circumference measured<br>• Medical history & medications recorded<br>• Clinical assessment of your skin and/or joints<br>• Blood sample taken<br>• Questionnaire pack to be completed (although these can be completed after the visit at home)<br>• Stool sample kit provided to complete at home |
| **At Home**<br>Within 2 weeks after Visit 1 | • 7-day diet questionnaire completed for the week prior to giving a stool sample and posted back with the stool sample |
| **Visit 2: Pre-treatment MRI Scan**<br>**Radiology MRI visit**<br>Can be combined with Visit 1 where possible<br>***Up to 1.5 hours*** | • You will be asked to fast for 3 hours before your scan appointment<br>• Height, weight and blood pressure will be measured<br>• MRI scan of liver, heart, lungs, kidneys, pancreas and spleen |
| **Week 0**<br>**At Home**<br>Email/phone call | • Confirmation of Bimekizumab start date (within the NHS this is usually 3-6 weeks after Visit 1) |
| **Visit 3: 24- Week Follow-up clinic visit**<br>**Hospital visit**<br>At routine clinic appointment where possible OR separate research visit<br>***Up to 1 hour*** | • Weight, waist & hip circumference measured<br>• Changes in medical history & medications recorded<br>• Clinical assessment of your skin and/or joints<br>• Blood sample taken<br>• Questionnaire pack to be completed (although these can be completed before the visit at home)<br>• Stool sample kit provided to complete at home |
| **At Home**<br>Within 2 weeks after Visit 3 | • 7-day diet questionnaire completed for the week prior to giving a stool sample and posted back with stool sample |
| **Visit 4: 24- Week Follow-up MRI Scan**<br>**Radiology MRI visit**<br>Can be combined with Visit 3 where possible<br>***Up to 1.5 hours*** | • You will be asked to fast for 3 hours before your scan appointment<br>• Height, weight and blood pressure will be measured<br>• MRI scan of liver, heart, lungs, kidneys, pancreas and spleen |

## Further information on study procedures

- **Consent**
  If you are interested to take part, the local study team will explain the study to you, answer any questions you might have and ask you to sign a consent form (a copy will be given to you for your records).

  The following study procedures are carried out twice; before you begin Bimekizumab treatment and 24 weeks after starting Bimekizumab treatment.

- **Height, weight, waist and hip measurements**
  Your height and weight will be measured to calculate your body mass index (BMI). Your waist and hip measurements will also be taken. Your height measurement will not be repeated at your 24-week follow-up visit.

- **Medical history and medication history**
  You will be asked some simple questions about your medical history which will include your psoriasis or psoriatic arthritis. Your current medications and any psoriasis or psoriatic arthritis medications will be recorded.

- **Blood samples**
  Blood samples will be collected at the same time as your routine tests. Approximately 50 mL (10 teaspoons) of blood will be taken for research purposes in addition to the 15 mL (3 teaspoons) taken as part of your routine clinic appointment. Therefore, you can expect up to 65mL (13 teaspoons) to be taken at each of the two clinic visits.

- **Clinical examination**
  The study doctor will assess your skin and/or joints.

- **Questionnaires**
  You will be asked to complete some questionnaires to assess your psoriasis or psoriatic arthritis symptoms and how these impact on your life. They should take no longer than 30 minutes to complete. If you prefer, these can be completed electronically at home by sending you an email with a link.


- **Stool sample**
  The local study team will provide you with a stool sample kit to complete at home. The kit will contain instructions on how to complete the stool sample and pre-paid packaging to post the stool sample back to the central laboratory at the University of Oxford.

- **Diet questionnaire**
  Included with the stool sample kit will be a 7-day diet questionnaire which should be completed for the 7 days prior to completing the stool sample. The diet questionnaire asks you to write what you ate each day and asks whether you took any vitamins, supplements and/or antibiotics. The completed diet questionnaire should be included in the same package when you post the stool sample back to the central laboratory at the University of Oxford. The information collected from the diet questionnaire will not be included in the study analysis, but it will help us to interpret the results from the analysis of your stool sample.

- **MRI Scan**

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The MRI scanner uses a strong magnetic field to create detailed images of the organs in your body. MRI is considered as a safe and non-invasive procedure as it does not use X-rays or any form of radiation. The research team will ensure that there is no reason that you should not have an MRI scan, e.g. heart pacemaker or metal clips inside your body. There are some contra-indications to MRI such as pregnancy or a pacemaker so the study investigator will discuss this with you before you are enrolled into the study.

The local study team, or a third party called Perspectum, will arrange your MRI scan and provide you with all the information you need before your appointment.

You will be asked to fast for 3 hours before the MRI scan. You may continue to drink sips of water, black tea or black coffee up until 30 minutes before your scan. This is in order to improve image quality. We advise that you do not wear contact lenses on the day of your scan.

In preparation for your scan and for your comfort and safety we may ask you to change into scrubs ("pyjama-style" top and trousers), available in a range of sizes. You may keep your underwear and socks on, but you will need to remove underwired bras. If you have a suitable non-wired bra you may wear this instead. Do not wear any fabrics that contain metallic threads or are silver impregnated (often marketed as anti-microbial/bacterial or anti-odour). Metal jewellery, including body piercing, must also be removed. If you wish to wear eye make-up to your scan, we will give you makeup removal wipes because you should not wear eye shadow or mascara in the scanner. If you wish, bring your own make-up to reapply. Lockers are provided to secure your personal belongings and clothing.

Before the scan, your height, weight and blood pressure will be measured. During the scan, you will be asked to lie on your back on a table that slides you into the scanner. You will be introduced to the scanner carefully and allowed to leave at any stage. The scan will take around 40-45 minutes and will take images of your liver, heart, lungs, kidneys, pancreas and spleen. As part of the scan, you will be asked to hold your breath for several seconds, with a maximum hold of around 10-15 seconds. Whilst in the scanner you will have a call button, which you can press if you need to stop

the scan or speak with the person operating the scanner. Some people may feel uncomfortable in the scanner, should you feel like you need to stop the scan, you can do so at any point by pressing the call button that informs staff to stop. They will then slide you out of the scanner.

If you think you might be claustrophobic, please talk to the researcher in advance, or let the person operating the scanner know before you start. Some of the scans are noisy, so we will give you earplugs to make this quieter for you. It is important that these are fitted correctly, as they are designed to protect your hearing. Headphones will be provided on the day to give you the option to listen to music during the scan.

In total the visit for the scan will take up to 1.5 hours.

## What should I consider?

If you are approached about or considered for taking part in this study, limited personal data will be recorded on a screening log. This will include your sex and age band. We collect this information to help us understand whether the people we approach for the study are representative of the wider population of patients with psoriatic diseases. Further details about how your data will be used, stored, and protected are provided in the "What will happen to my data?" section.

Before joining the study, you will be screened to check whether it is suitable and safe for you to take part. You will therefore not be able to participate if:

- you have previously received Bimekizumab, or any other drug that works in a similar way for any medical condition
- you have a different form of liver disease including autoimmune hepatitis, viral hepatitis and Wilson's disease
- you are unable to have an MRI scan (for instance, because of metal implants, women who are pregnant, people with extensive tattoos, pacemakers, shrapnel injury or severe claustrophobia)
- you regularly drink more than 28 units of alcohol per week (28 units roughly equates to 3 bottles of wine or 14 pints of beer) or have a history of binge drinking
- you are currently involved in, or planning to join, another research study

This is to make sure participation is safe for everyone.

You will be able to continue all of your current medications with no changes.

After joining the study, if it is not possible for you to complete your pre-treatment MRI scan and/or you do not eventually commence Bimekizumab treatment, you will be withdrawn from the study by the study doctor and no further study procedures will occur. We will destroy any research samples collected from the Screening visit. You would be withdrawn from the study because without the pre-treatment MRI scan and commencing Bimekizumab treatment, we would be unable to answer the research question.

It is important to note that we do not carry out MRI scans for diagnostic purposes, only for research. Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor's appointment. Occasionally, however, a possible abnormality may be detected. In this case, we would have the scan checked by a doctor. If the doctor felt that the abnormality was medically important, you would be contacted directly and further assessment arranged as necessary. You would not be informed unless the doctor considers the finding has clear implications for your current or future health. We will send a report to your doctor if your MRI scan results show you may have suspected

liver disease so that your doctor can share this with you and arrange further investigation if necessary. All information about you is kept strictly confidential.

## Are there any possible disadvantages and risks of taking part?

When you attend for your clinic visits, it will take longer to have the full assessments and to complete the extra questionnaires. The clinic visit should take around 60 minutes to complete and the questionnaires should not be overly sensitive in nature but you can complete these in private if needed. Having the additional blood samples may result in bruising or occasionally patients can faint but research samples will be taken at the same time as your routine NHS blood tests wherever possible.
The medication used in this study is prescribed on the NHS for treatment of psoriasis or psoriatic arthritis. However, as with any medication, there are always associated risks, which you should discuss with your doctor.

MRI is safe and does not involve any ionising radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. You will be asked to answer some safety questions to determine if you can take part. Normally, we would need more information before you take part in the research MRI scan if you have a heart pacemaker or stent, mechanical heart valve, mechanical implants such as an aneurysm clip, joint replacement (e.g. hip/knee), or if you carry other pieces of metal that have accidentally entered your body.

While there is no evidence that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit. We do not test for pregnancy as routine so if you think you may be pregnant you should not take part in this study.

While very rare, tattoos can occasionally warm up in the scanner. Please inform the person operating the scanner immediately if you feel any heating. If you have a new tattoo, you should not take part in a scan until 48 hours after receiving the tattoo.

## What are the possible benefits of taking part?

There may be no direct benefit to you from taking part in this study. However, as part of the study you will undergo two MRI scans that you would not normally have outside the research setting. These scans may detect changes that might indicate the presence of liver disease or other abnormalities.

## Will my General Practitioner (GP) be informed of my participation?

If you join the study, we will notify your GP that you are taking part in the study and what the study entails. Your GP will be made aware so that they can support you.

If the scan shows any changes that may suggest liver disease, this information will also be shared with your GP to help ensure you receive appropriate follow-up care.

## Will my taking part in the study be kept confidential?

Created by Alhaliza Risma Elvariani from Noun Project

Yes. Wherever possible, your study records will be identified only by a code. With your permission, the central study team at University of Oxford will only use your name and contact details (email/postal address) so we can get in touch with you to complete study questionnaires, and to send you the results of the study.

Your information will be kept secure and confidential. We will minimise the identifiable personal data collected and it will be stored securely such as in secure locked cabinets within secure buildings at each site. When transferring and analysing clinical, and questionnaire data, we will make sure that no identifiable data is included so that study records are identified only by a code. Your MRI images will be de-identified before it is transferred. This means information that could directly identify you (such as your name, NHS number or date of birth) will be removed. Your MRI images will include your sex, it is important for research analysis.

Any samples you provide will be labelled with a code and your initials. We include your initials on samples to help prevent mix-ups and ensure they are processed accurately in the laboratory. You cannot be identified from the code and initials alone.

Confidentiality will be maintained as far as it is possible unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies but we would discuss it with you first.

Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

## Will I be reimbursed for taking part?

You will not receive any payment for taking part in this study as the visits for the study have been carefully timed to fit in with your usual NHS assessments in the clinic. However, your clinic visit and/or your MRI scan may require a separate visit depending on the local study team and MRI scanner availability at the hospital. If your clinic visit and/or MRI scan fall outside your normal NHS clinic visits, you will be reimbursed up to a maximum of £30 for your travel expenses (whether travelling by car, public transport, or taxi) for each visit. Please keep hold of your receipts so you can claim the travel expenses from your local study team.

## What will happen to the samples I give?

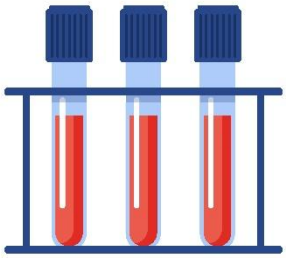
Samples for the study include blood and stool samples collected at Screening and at the 24-week visit. The blood samples will be processed and frozen for storage until study completion for subsequent analysis at the central laboratory at University of Oxford. The stool samples collected at home and returned by post to the central laboratory will also be processed and stored until study completion for analysis.

At some research sites, the Enhanced Liver Fibrosis (ELF) blood test will be carried out by a specialist laboratory outside the hospital. This means that your blood sample may be sent securely to an external laboratory for testing. Your sample will be handled carefully and confidentially at all times.

To help keep your information confidential, your samples and any information recorded about you in this study will be assigned a study code that is used instead of your name and other identifiers.

Samples will also include your initials to ensure accurate handling, but you cannot be identified from the code or initials alone. However, your DNA is unique to you so it can never be completely anonymous.

A variety of tests will be performed to assess the degree and pattern of inflammation using cells from your blood and the DNA from your blood and stool samples. We will determine the levels and activity of the cells that cause inflammation and damage in psoriasis or psoriatic arthritis and how treatment affects these cells. The DNA from stool samples will be used to study the composition of "gut flora" (bacteria, viruses and fungi living in your digestive system) and how this may be linked to the disease process. The DNA from your blood will be used to understand how inflammation affects your immune system.



With your permission, at the end of the study, we will store any remaining samples, for use in future studies. Your samples and linked clinical data will be used in a form that does not identify you, mainly by researchers involved with this study but also ethically approved research projects which may take place in hospitals, universities, non-profit institutions or commercial organisations worldwide. Because they will be shared in a form that does not link back to you it will not be possible to withdraw them after they are shared. If you choose not to give consent for this, your samples will be securely destroyed at the end of the study.

## What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you from your medical records for this research project. We will share your information related to this research project with the following types of organisations;

- third-party company providing the MRI scan software and analysis of the scan data.
- third-party laboratory providing the Enhanced Liver Fibrosis (ELF) test at selected research sites

This information will include your:

- full name
- Date of birth
- Contact details (telephone number and e- mail address)
- Sex

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure by:

- Access limited to essential personnel only
- Data has been de-identified as soon as possible
- Paper- based data is stored in locked filing cabinets/ storage with access restricted to authorised personnel

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of 15 years in line with the Funder's requirement. Once the retention period has finished, the study data will be kept in a way that does not identify you.

## International Transfers

Your personal data will not be shared outside the UK.

## What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [please insert details of any specific bank / repository]

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

- asking one of the research team balance@ndorms.ox.ac.uk
- sending an email to balance@ndorms.ox.ac.uk
- calling us on 01865 613476
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: https://compliance.admin.ox.ac.uk/research-data.

If you would like to find out more about the use of confidential data in research, the Health Research Authority (HRA) has developed a general information leaflet which is available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/.

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share

your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

Authorised MRI scanning centre personnel at the local NHS Trust, the MRI company Perspectum and the research team will have access to the MRI imaging data. MRI imaging data is assigned a unique ID as it is collected and stored in a secure database on University managed IT systems. Due to the nature of the MRI images, they remain potentially identifiable, even after we destroy your personal details. Imaging data will be stored on archive tapes at the MRI location and kept indefinitely, for quality control, and to facilitate further use of the scans where permission has been given.

During the study, de-identified data on any side affects you may experience while taking Bimekizumab will be shared by the central study team with the Funder, UCB (manufacturer of Bimekizumab). At the end of the study, the central study team will provide an end of study report to the Funder, UCB, which details the results of the study. It will not be possible to identify you from the data within the end of study report.

The local NHS Trust or local study team will use your name, NHS number, home address, and contact details, to contact you about the research study, and to oversee the quality of the study.

The local research team will use your postcode to work out the 'Index of Multiple Deprivation' (IMD) score, which is a widely used measure in public health research and policymaking relating to health inequalities. The data will be stored and analysed in a way that ensures that participants cannot be identified from it. Collecting this information will help us to see whether the research we are carrying out is inclusive and representative of the whole UK population.

We will collect information about your ethnicity, people from different ethnic backgrounds can have different risks of developing liver disease. By collecting information about your ethnicity, we can better understand these differences and make sure our research benefits everyone.

A copy of the consent form from this study will be kept in your medical records for as long as those records are retained.

## What will happen if I don't want to carry on with the study?

If you do not want to carry on with the study, you can change your mind at any time. Withdrawal will not affect the care you receive. Your local study team will make sure that any safety checks are completed. They may arrange a follow-up or final visit if needed, to confirm that there is no ongoing safety concerns related to the study procedures.

If you withdraw, no further study procedures will occur and no further data will be collected but the data collected up to the point of withdrawal will be kept and used for the purpose of the study unless you state otherwise. Any blood or stool samples which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet.

If, during the course of the study, you were to lose the mental capacity to continue in the study, you would be withdrawn from the study and no further data or samples will be collected from you. Any data or samples already collected up to the point of loss of mental capacity will still be used in the study.

## What will happen to the results of this study?

At the end of the study, you will continue to receive care for your psoriasis or psoriatic arthritis at your hospital/ clinic.

With your permission, we will write to you at the end of the study (by post or email as per your preference) once we have the study results to give you a brief summary of what we found. We expect this will be within 12 months of the last participant completing their last visit but it may be longer.

We will publish the research in a scientific medical journal and present the findings at medical conferences. This can potentially take several years to be fully completed. Any information we publish, in any format, will never reveal your identity or contain any information that could be linked to you specifically.

Relevant newsletters, social media, and patient-facing charities may also be used to communicate the results of the study to the wider community once they are available.

## What if we find something unexpected?

If we find anything unexpected during the MRI scan that may have implications to your health, your clinical care team will be made aware and they can follow up with any appropriate investigation and/ or treatment.

## What if there is a problem?

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact the Chief Investigator, Professor Laura Coates, at balance@ndorms.ox.ac.uk, 01865 613476 or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

NHS indemnity operates in respect of the clinical treatment provided.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact [insert local NHS site phone number and email from the local PALS website].

## How have patients and the public been involved in this study?

Members of our Patient and Public Involvement (PPI) were involved in reviewing this Participant Information Sheet and Consent Form and all other documentation. We will continue to involve them as the study goes on. To learn more about how patients and the public are involved in clinical research, visit the links below.

- https://www.nihr.ac.uk/get-involved/public-involvement
- https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/public-involvement-newsletter/

## Who is organising and funding the study?

The study is being sponsored (organised) by the University of Oxford and funded by UCB, the manufacturer of Bimekizumab. UCB provides financial support to conduct the study but will not have access to your personal information.

## Conflicts of Interest

Prof Laura Coates, who is the doctor (a Consultant Rheumatologist) leading this study, has received research support, worked as a paid consultant and has been a paid speaker for the funder UCB. However, Prof Laura Coates nor the other researchers involved in this study have any financial or personal interest that could influence the results of this study.

## Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by [insert name] Research Ethics Committee.

## Further information and contact details:

For further information please contact local study team by telephone [insert local study team number] or email [insert local study team email address].


## Thank you for reading this information and for considering taking part.