[NHS Trust Logo]

UK Heart Failure with Preserved Ejection Fraction Registry (UK HFpEF)

PARTICIPANT INFORMATION SHEET
Version 4.0 27/03/23

Summary
We are inviting you to take part in a research study. With this study we are aiming to improve the quality of life and outcome of patients with heart failure with preserved ejection fraction in the future. The study involves you giving a blood sample (which will be used for a range of tests including genetics), completing a questionnaire, and agreeing that your past and future medical, health, and social care information can be collected and used for research. You may also be asked to do a walk test and have an additional 5 minutes of scanning if you are already having a MRI scan. By taking part in this study, you may also be offered the opportunity to take part in other studies related to heart failure with preserved ejection fraction.

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 carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

Thank you very much for taking the time to do so, and for considering taking part.

What is the purpose of the study?
Heart failure occurs when the heart is no longer able to pump blood around the body properly. It can cause breathlessness, swollen feet and ankles, and tiredness. In about half of patients with heart failure, one measure of the heart's pumping function, called the 'ejection fraction', is normal. This type of heart failure is called heart failure with preserved ejection fraction, or HFpEF.

HFpEF remains poorly understood. It is not clear why some people develop HFpEF, or what determines the severity of the condition. Treatment options may be limited.

Patients with HFpEF have traditionally been treated as if they all have the same condition. However, it is becoming clear that the diagnosis of HFpEF includes patients with a range of different underlying heart and blood vessel abnormalities, as well as different underlying conditions which may contribute to their heart failure.

This study is called the UK Heart Failure with Preserved Ejection Fraction Registry, or UK HFpEF. It aims to gain a better understanding of why people develop HFpEF, develop better tests to diagnosis it, identify and test new treatments, and follow the health of the people taking part over many years. We hope that many thousands of patients with HFpEF will take part.

Why have I been asked to take part?
You are being asked to take part because you have been diagnosed with HFpEF.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you decide to take part, a member of the study team will ask you to sign a consent form. If you decide to take part and then change your mind, you are free to withdraw from the study at any time and without giving a reason. If you decide not to take part, your decision will not affect the standard of healthcare you receive.

What does taking part involve?
If you agree to take part, we will ask you to the following, which we expect to take up to around 45 minutes:

- Sign a study consent form.
- Provide your name, date of birth, sex, ethnicity, NHS number, contact details (including address, email and phone numbers, if available), and details of your GP, which will be stored securely.
- Complete a health and lifestyle questionnaire.

- Have an assessment of your physical status. This may include, for example, assessment of symptoms and signs of heart failure, vital signs and frailty.
- Give a blood sample, up to a maximum of 50ml (approximately 10 teaspoons), to allow a wide range of laboratory analyses. This is in addition to any blood sample you provide as part of your routine care.
- We may ask you to do a walking test to measure your exercise capacity. This involves you walking at your own pace for up to 6 minutes, for example up and down a corridor, and a member of the study team measuring how far you walk. You can stop at any time. Whether or not we ask you to do this will depend on the facilities available and your ability to walk.
- If you are having a MRI scan as part of your clinical care, we may ask you to have an additional 5 minutes of scanning, so that additional images and measurements can be made that may allow us to better understand how your heart functions.
- Agree to the collection of information relevant to your past and future health from medical, health, social care and other health-related records, which are collected or held in local, regional and national systems. The information collected may include: general practice (GP) records, hospital records, national health-related data collected by national organisations (such as NHS Digital, the Office for National Statistics, Public Health Scotland, Research Data Scotland, the SAIL Databank for Wales), national or local audit data, or any other source of information relevant to your health. Information that may be collected includes, but is not limited to: medical history, diagnoses, symptoms, signs, prescriptions, medications, vaccinations, referrals to various health professionals, laboratory tests (for example, on your blood and urine), scans (for example, imaging scans of your heart, brain and body), information on hospital attendances and admissions, death registry information, lifestyle, and any other health-related information.
- You may be asked to participate in additional, approved research studies that may be related to UK HFpEF. If you are eligible and interested to take part, you will be provided with additional information. Your consent for such studies will be sought separately. You are under no obligation to take part in such studies.

What will happen to my information and blood sample?
In this study, we will use information from you, from your health-related records, and from laboratory analyses of your blood sample. You donate your information and blood sample as a gift, without receiving a payment.

Manchester University NHS Foundation Trust, based in the United Kingdom, is the sponsor for UK HFpEF and will act as the study's data controller. This means that Manchester University NHS Foundation Trust is responsible for looking after your information and sample and for ensuring their proper use.

How will you look after and use information about me?
Best ethical and legal practice are followed to ensure that all information collected will be handled confidentially. All study information (or data) will be held in a research database. The research database is de-identified and 'pseudonymised'. This means that personal details that might identify you (such as name, full date of birth, NHS number, address and contact details) will be removed and will be replaced be a code that is unique to you. This code is called a 'pseudo-identifier'. Personal details that might identify you will be held in a separate study administration database. Only a very small number of named members of the study team will be able to access your personal details in the study administration database. These study team members will be determined by the Steering Committee (see section 'Who is running the study?' for a description of the Steering Committee). Researchers who work with the study data in the research database will have no access to your personal details. An electronic copy of your consent form will be uploaded and stored securely alongside your personal details in the study administration database.

Pseudonymising allows the study team to connect your study information, sample, and the results of your sample analysis. The link between the pseudo-identifiers and your personal details will be kept securely in the study administration database.

In some circumstances, for example to fulfil General Data Protection Regulation (GDPR) data access requests, we may be required to combine participants' study data with their personal details. Study team members who would undertake such activity will be trained and will have specific approval from the Steering Committee and study sponsor.

Why do some members of the study team need to access my personal details?
We need this information to do the research. For example, we may need to contact you to arrange study visits, to retrieve information from your health and social care records or from nationally held health-related databases, and so that we can contact you about future research studies. This information is also required so that your records can be checked to make sure that the research is being done properly. Manchester University NHS Foundation Trust will keep your personal details for 10 years after the study has finished so that the results of the study can be checked if required. We will keep all information about you safe and secure.

How will you look after and use my sample?
Your sample may undergo some initial processing and storage at your local NHS site before being transferred to a secure processing and storage facility in the United Kingdom, such as the National Institute for Health Research National Biosample Centre in Milton Keynes.

A wide variety of laboratory analyses may be performed on the sample for research purposes as part of this study or future research. These will help us to:

- improve our understanding of HFpEF and why some people develop it,
- identify different types of HFpEF,
- support the development of new diagnostic tests,
- support improved guidance on patient management,
- support the development of new treatments and understand why people respond differently to treatments,
- improve or support other aspects of HFpEF research and patient management.

The analyses may also support future studies that you may be contacted about being involved in.

Sample analyses may include analyses of your genes as well as of proteins, lipids, carbohydrates and a wide range of other analyses. The analysis of your genes may include determining the sequence of part or all of your DNA code. Your sample, and the information generated from the analyses of it, will be linked to all of your other information collected as part of the study.

Your sample will be labelled with a pseudo-identifier and analyses will be done on pseudonymised samples. No personal details that might identify you will be kept with the sample or passed to external teams carrying out sample analyses.

Will my information and sample be shared?
Your pseudonymised study information, including genetic information, may be shared for research purposes with researchers or organisations, including commercial companies, in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America, where data protection laws may differ.

Analyses of your pseudonymised sample, including genetic analyses, will be carried out by the most suitable team. This may be within facilities run by the NHS, research organisations or commercial companies. The facilities may be based in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America.

Requests for access to data and samples will be managed by the Steering Committee. Release of data or samples to researchers or organisations requesting access will be covered by specific agreements. The agreements are legally binding, and will regulate the use of data and samples, and ensure that standards are maintained.

The results of analyses of study information and samples will be presented in reports, publications and presentations. You will not be identified personally in any of these. At the end of the study, information held in the research database may be transferred to research or scientific archives for use in scientific and medical research.

What happens if an invention is made using my information and/or samples?
UK HFpEF is operating on a non-commercial basis. It will not sell your sample or data to make a profit and will not allow anyone else who is working with them to do so either. However, if data or samples are made available to other research institutions or commercial companies, a fee may be charged to cover the UK HFpEF study team's operational costs. Your sample and data may help researchers in the public and commercial sector to make an

invention, for example, develop a new product to diagnose or treat heart failure. If an invention results from the research undertaken with your data or sample, you will not receive any compensation, recognition or payment. UK HFpEF and its partners in the public sector may work together with commercial companies to develop inventions for the benefit of patients, and we hope that such products will be brought into use to improve healthcare.

Where can I find out more about how my information is used?
You can find out more about how we use your information:

- At https://research.cmft.nhs.uk/getting-involved/gdpr-and-research
- At the UK HFpEF study website
- By asking one of the UK HFpEF research team
- By contacting the UK HFpEF research team [site to insert contact details]
- By contacting the Sponsor's Data Protection Officer (dpo@mft.nhs.uk)

How does the process of being contacted about being involved in other research studies work?
UK HFpEF supports recruitment of participants to other research studies. Participants will generally be identified for such studies according to their characteristics, such as their medical history, scan measurements, sample analysis, genetics, or other features. Providing patients for other studies means that research can be conducted more efficiently, and it gives patients who would like to take part in other studies the opportunity to do so. Examples of other studies may include, but are not limited to, trials of new medicines, assessments of new diagnostics, or studies evaluating patients with other procedures.

Such studies will require their own approvals. The process by which other studies would contact you will be overseen by the UK HFpEF Steering Committee. You will be provided with the full information regarding each study, and you will be free to decide whether or not to participate at the time. You will be invited to take part in no more than 4 other studies in any 12 month period. If you are contacted to take part in a future study, it does not mean that your health is at risk.

What are the benefits of taking part in UK HFpEF?
There may be no direct benefit for you. However, patients who take part in research may have a better understanding of their condition by spending more time with the research team and having the opportunity to ask questions. By taking part you will help to improve our understanding of HFpEF and support the development of new diagnostic tests and treatments.

What are the risks of taking part in UK HFpEF?
Blood sampling: Qualified staff will perform the sampling, but it can sometimes cause discomfort and a small bruise

You may be asked to do a walk test: This simply involves you walking at your own pace for up to 6 minutes. You can stop at any time. There are no specific associated risks.

If you are having a MRI as part of your clinical care, you may be asked to have an additional 5 minutes of scanning: This is not associated with any additional risk.

Can I find out the results obtained from my sample and information?
The UK HFpEF team will not feedback any results obtained from your participation in the study to you, and results will not be included in your clinical record or shared with your doctors. They will be used solely for the purposes of research. We will put information about study progress and findings from the study on the UK HFpEF website.

What are my choices about how my information and sample are 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. If you choose to stop taking part in the study, we will ask you to choose one of the options set out in the next section. We need to manage your records in specific ways for the research to be reliable, which means that we will not be able to let you see or change the data we hold about you.

What if I no longer want to be a part of UK HFpEF?
You can stop being part of the study at any time, without giving a reason. If you choose to stop taking part in the study, please contact the research team where you enrolled in the study, or the central research team. The contact details are given at the end of this information sheet. We will ask you to choose one of the following options:

1. No further contact with you. We will stop further contact with you. However, you allow research using your information and sample to continue, and you allow continued collection of information from your medical, health, social care and other health-related records, which are collected or held in local, regional and national systems.

2. No further contact with you and no further analysis of your sample. We will stop further contact with you. Any remaining sample from you that has not already been used for analysis will be destroyed so it cannot be used in new analyses. However, you allow research to continue using information already held about you, including from previous analysis of your sample, and you allow continued collection of information from your medical, health, social care and other health-related records, which are collected or held in local, regional and national systems.

3. No further contact with you and no further research using your samples or information. We will stop further contact with you. Any remaining sample from you that has not already been used for analysis will be destroyed so it cannot be used in new analyses. We will stop collecting information from your medical, health, social care and other health-related records. No further research will be conducted using the information we hold about you.

If you choose to stop taking part in the study but it is not possible to confirm your preference, Option 1 will be implemented. For all options:

- Your personal information will be retained in an archive so that a record remains of your initial study consent and the withdrawal process.
- We will keep information about you that we already have. Existing data cannot be destroyed. Data that has been securely distributed, analysed or used in reports or publications cannot be reversed or withdrawn.
- If you choose options 1 or 2 you also agree that your existing data can continue to be used for future analysis. If you choose option 3, existing data will not be used for future analysis.
- It will not be possible to destroy sample already prepared, distributed for analysis, or analysed.

Who is running the study?

The sponsor of the study is Manchester University NHS Foundation Trust. The study is funded by the National Institute for Health Research (NIHR), with support from the NIHR–British Heart Foundation Cardiovascular Partnership. The initial funding supports setting up the study and recruiting approximately the first 875 patients. Further funding is being sought in parallel to continue this study to complete recruitment of 10,000 patients. The study has been reviewed by the National Research Ethics Service Committee and the Health Research Authority to make sure that it is scientifically and ethically acceptable. A UK HFpEF Steering Committee will oversee the study and the study processes. This Committee is made up of researchers, a representative from the sponsor, and patients.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of your research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the NHS Patient Advice and Liaison Service (PALS) or equivalent. Members of your local hospital team should be able to provide this information to you.

Every care will be taken in the course of this study. However, in the unlikely event that you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against Manchester University NHS Foundation Trust, but you may have to pay for your legal costs. The normal National Health Service complaints procedures should be available to you.

Who do I contact for further information?
If you have any questions about the study, please talk with a member of the research team (Please note: No medical advice can be provided. If you have questions about your clinical care, please contact your clinical team).

Research team at [Insert name of site]: [Insert contact details of site PI/research team]

Central research team: email UK-HFpEF@mft.nhs.uk or Tel. 0161 291 4075

We would like to thank you for taking the time to read this information sheet and potentially participating in the study.

[NHS Trust Logo]

UK Heart Failure with Preserved Ejection Fraction Registry (UK HFpEF)

CONSENT FORM

For site use only:																				
Site Name:																				
Participant Study Number:																				
Participant Surname:																				
Participant First name:																				
Participant DOB:			/			/														

To be completed by the participant

Once you have read and understood the information in each section, please enter your initials in each box. At the end of the form, print, date and sign your name.

You must agree to all statements to take part

1. **Taking Part**
   a. I have read and understood the information sheet for this study (Version 4.0,27/03/23). I have had the opportunity to ask questions and have had these answered satisfactorily.
   b. I understand that participation is voluntary and that I am free to withdraw from the study at any time, without giving a reason, and without my care being affected. If I withdraw, I understand that I will be asked to choose one of the options explained in the information sheet.

Initial here to confirm you have read and understand this section	

2. **Data**
   a. I agree that the UK HFpEF team may collect information relevant to my past and future health from medical, health, social care and other health-related records, which are collected or held in local, regional and national systems. The information collected may include: GP records, hospital records, national health-related data collected by national organisations (such as NHS Digital, the Office for National Statistics, Public Health Scotland, Research Data Scotland, the SAIL Databank for Wales), national or local audit data, or any other source of information relevant to my health.
   b. I understand that national organisations, such as NHS Digital, may over time change their name or status. For the avoidance of doubt, I agree to any medical, health or social care-related information held via these types of organisations to be accessed, collected, and used as part of UK HFpEF.
   c. I agree for the long-term storage and usage of my data, including in the event of my incapacity or death.
   d. I understand that my data will be held using a unique code (pseudonymised). All my data may be linked together, including my samples and information obtained from my samples, and analysed.
   e. I agree that my personal and contact details, such as my name, full date of birth, NHS number, address and contact details, and details of my GP, can be stored securely as part of this study, as described in the information sheet, and used for the purposes set out in the information sheet.
   f. I agree that my pseudonymised study data may be shared for research purposes with researchers or organisations, including commercial companies, in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America.
   g. I agree that information produced by analysing my data, including analysis of my samples, may be included in reports, publications or presentations. At the end of the study, I agree that my study data may be transferred to research or scientific archives for use in scientific and medical research.
   h. I agree that a copy of this consent form may be uploaded to the study database.

Initial here to confirm you have read and understand this section	

3. Blood sample

a. I agree to give a blood sample of up to approximately 50ml.
b. I understand that I am donating my blood sample and information about me as a gift.
c. I understand that my sample will be labelled with a unique code (pseudonymised).
d. I agree for the long-term storage and use of my sample, including in the event of my incapacity or death.
e. I agree to my sample being analysed as outlined in the information sheet. This may include determining the sequence of part or all of my DNA (genetic) code.
f. I understand that my sample, and the information generated from my sample, will be linked to all of the other information collected as part of the study.
g. I understand that analysis of my sample may take place within NHS facilities, research facilities or by commercial companies, and may take place in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America.
h. I agree that my sample may be used in future research without my further permission.

Initial here to confirm you have read and understand this section	

4. Results

I understand that the UK HFpEF team will not feedback any results obtained from my participation in the study to me.

Initial here to confirm you have read and understand this section	

5. Other studies

I understand that I may be invited to participate in other research studies based on data held or accessed about me, and/or analysis of samples I have donated. I will be provided with full information about these studies, when and if I am contacted. I understand that I am free to decide whether or not to take part in these studies.

Initial here to confirm you have read and understand this section	

By signing this form, you understand that you are agreeing to all of the sections above

Your first name and surname (BLOCK CAPITALS)			
Your signature		Date	

To be completed by the person taking consent			
First name and surname (BLOCK CAPITALS)			
Signature		Date	

Please file the original copy of this form in the site file (electronic or paper-based). Copies should be provided to the participant, included in the participant's health record and uploaded to the study database