Delete this line, then print on Trust/Hospital headed paper

Personalising treatment for myeloma patients based on how well they initially respond to a period of NHS treatment and their overall fitness level

Bone marrow sharing:
We would like to use some of the **bone marrow** from your planned bone marrow tests

You are currently having tests to find out if you have a disease called myeloma. This is sometimes called multiple myeloma. If the tests confirm you have myeloma, your hospital doctor may invite you to take part in a research study called iFIT. iFIT is a phase 3 clinical trial of an investigational medicinal product.

iFIT is looking at personalising treatment for myeloma. We will look at how each person responds to a period of an NHS treatment called DRd, and each person's level of fitness. DRd is a combination of three medications called daratumumab, lenalidomide and dexamethasone. People with myeloma usually receive this treatment for as long as it is working, until their myeloma progresses (gets worse). In this research, people with myeloma would have this treatment for around 6 months to start with. Then we will look at their data to personalise their further treatment to potentially be:

- More effective for those who have detectable myeloma cells at that time
- A fixed amount of time for those who do not have detectable myeloma cells at that time
- Gentler for those with a lower fitness level.

We are a group of doctors, people affected by myeloma, and myeloma researchers. We are from the University of Leeds and around the UK. We have set up this research.

It is completely up to you whether you agree to share your sample with us. If you are interested in taking part in iFIT, we ask that you share part of your bone marrow sample from the tests you are already having. This is so you won't need to have another bone marrow test at the start of iFIT.

Agreeing to share your sample with us does not mean you have to take part in iFIT.

How will we use information about you?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the information in case we need to check it and for future research.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this (see **Appendix 1**).

To help you understand the research, the information is split into several documents:

iFIT document	This document	When will I receive this?	What is being asked of me?
Bone marrow sharing	✓	When having tests to find out if you have myeloma	Do you agree to share a sample of your bone marrow from your planned tests?
Study registration		If you are diagnosed with myeloma	Do you agree to be monitored whilst having the NHS treatment DRd, and for us to collect your data and samples?
Randomised study treatment		After completing a period of the NHS treatment DRd	Do you agree to continue to take part in the research and be randomly allocated to a further treatment based on your data?
Additional information [optional - you don't have to read this before you make your decision]		At the same time as the 'Study registration' document above	Nothing is being asked of you here. This is additional information you may find interesting or helpful.

Large-print and electronic versions of all documents are available. Visit https://ctru.leeds.ac.uk/ifit.

Ask your hospital doctor or nurse if you would like to have a copy of any of the above documents. This document has all the information you need to know now, but you may want to learn more about the research.

Please look through all the information in this '**Bone marrow sharing**' document before you decide.

Once you have read this information, your hospital doctor or nurse will talk to you about the research again and you can ask any questions you like.

Contents page

Who can I contact if I have more questions?

If you have any questions about this research, please talk to your **<<enter Consultant, Doctor, Nurse, Researcher>>**:

<< Enter name >>

<< Enter contact details >>

What sample would I give?

You will be having a procedure known as a ‘bone marrow biopsy’ as part of your usual care. This is a procedure to remove a sample of fluid, cells, and bone marrow for examination and testing.

We would like to take a little extra bone marrow fluid (about 2 teaspoons (10mL)) for the purposes of this research. This would be taken during the same procedure, so you do not need to do anything extra.

Can I take part in iFIT without sharing my sample?

We need a sample of your bone marrow fluid before you take part in iFIT so that we can monitor any changes throughout your treatment. You do not have to share the sample now. However, we are asking you now as you are already having tests where bone marrow fluid is being collected.

You can provide the sample later, but this would mean you would need to have another ‘bone marrow biopsy’ or ‘bone marrow aspiration’ (a procedure to remove a sample of fluid only).

There may be reasons why you cannot take part in iFIT, or your hospital doctor might advise that it isn’t suitable for you. We do not know whether you will be able to take part yet.

What will happen to my sample?

Some of your sample will be sent to your hospital laboratory to:

- Help identify whether you have myeloma, and
- Look for certain changes in the genes of any myeloma cells that might be present.

This will happen even if you do not take part in iFIT.

The bone marrow sample you share for this research will be split and sent to the iFIT laboratories:

- The Haematological Malignancy Diagnostic Service (HMDS) in Leeds to look at the amount of myeloma in your bone marrow, if any.
- The Royal Marsden and the Institute of Cancer Research in London, and the Leeds Institute of Medical Research. Researchers there will use the sample to learn about why some people respond better to the treatment than others, or why the disease has progressed (got worse), if the disease is present. They will also see if the sample can give a better idea of each person's level of fitness.

We may also share some of your sample with scientists in other research institutes or laboratories in the UK to analyse results for this research.

Some of the iFIT laboratories will extract and/or analyse substances including protein, DNA and RNA from your sample. Researchers there will look to see if any genetic or other patterns can be found in different people and how these relate to several aspects of iFIT research including better understanding frailty, ageing, myeloma and drug response and resistance.

The results from the iFIT laboratories will not be shared with your hospital doctor, as they are not relevant to your individual care.

What happens if I do not have myeloma or a related disease?

If you do not have myeloma or a related disease, your sample that is sent for this research will be securely destroyed.

Some material may need to be kept by the laboratories for quality control purposes.

Once the samples have been processed by the laboratories, the information linked to them cannot be deleted and this will remain on laboratory systems in line with usual NHS processes.

Optional use of your sample for future research

Your sample is helpful and could help people with myeloma in the future, even if you have a related disease that is not myeloma.

If you are diagnosed with myeloma or a related disease, we would like your permission to store and use your sample for future research.

This is optional. If you agree to share your sample with us, you do not have to agree to this.

What if I change my mind about my sample being used for future research?

If you later request that your sample is no longer used for future research, the sample will be destroyed. We won't do a further analysis of the sample, but we will continue to use the data already collected.

Some material from your sample that has already been processed may need to be kept by the iFIT laboratories for quality control purposes.

Appendix 1

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Identifiable information, such as your full name, NHS number (or CHI number for Scotland), and date of birth.
- Results from your medical tests, when they are relevant to the research.
- Results from samples analysed at the laboratory at your hospital, to look for certain genetic abnormalities.
- Results from the analysis of your samples sent to the iFIT laboratories (such as HMDS, LIMR, and RM/ICR).

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.

The University of Leeds is the sponsor of this research.

The University of Leeds is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Laboratories. Your sample will be sent to the iFIT laboratories alongside information about you such as NHS number (or CHI number for Scotland), date of birth, sex and initials. Your sample sent to HMDS in Leeds will also include your full name. This helps ensure your sample is correctly identified as yours.
- Regulatory bodies.
- NHS England or other central UK NHS bodies.
- Other organisations with trusted researchers who are working on research in the public interest. We will only do this for worthwhile research projects with all appropriate approvals.

We will keep all information about you safe and secure by:

- Carefully planning how we will collect and use your information, so that we know it will be done securely.
- Only using information that will identify you when we really need to.

- Holding information in very secure databases so that it would be very difficult for unauthorised people to access it.
- Storing any paper documents in locked cabinets, accessible only to people who need access to run the research.
- Training all our staff on how to use people's information correctly.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Share the information we collect in this research study for other research projects.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Other organisations with trusted researchers who are working on research in the public interest. We will only do this for worthwhile research projects with all appropriate approvals.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by laws and other rules about research. These say it must be possible to check the results of the research study for a period of time after it has finished. This means we will need to keep your identifiable information until at least 25 years after the research study has finished. The study data will then be fully anonymised and securely archived or destroyed.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your hospital. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the research. You can also object to our processing of your data. 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.

Where can you find out more about how your information is used?

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:

- Our leaflet https://ctru.leeds.ac.uk/privacy-cookies/how-we-use-personal-data/ and www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to DPO@leeds.ac.uk, or
- By ringing us on +44 (0)113 343 7641.

Delete this line, then print on Trust/Hospital headed paper

Participant ID:	Initials:
Date of Birth:	NHS number (or CHI number for Scotland):
ISRCTN:	Principal Investigator:

PARTICIPANT INFORMED CONSENT DOCUMENT FOR BONE MARROW SHARING

Please initial for each statement

1. I confirm that I have read through the information about sharing my bone marrow sample and I have had the opportunity to ask questions.

_ _ _ _
Initials

2. I understand that sharing my bone marrow sample is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.

_ _ _ _
Initials

3. I understand that my bone marrow sample will be sent to the iFIT laboratories along with information about me, which will include NHS number (or CHI number for Scotland) and may include my name.

_ _ _ _
Initials

4. I agree to my bone marrow sample being stored and used for research investigations that form part of iFIT (UK-MRA Myeloma XVIII) and understand that this will include genetic research. _ _ _ _ Initials

5. I agree for my details (which will include my date of birth and NHS number (or CHI number for Scotland)) to be submitted to NHS England or other central UK NHS bodies so that information about my health may be obtained by the CTRU. _ _ _ _ Initials

6. I agree that information collected about me in this research can be shared with researchers outside the original team, so they can do additional research projects. This could include researchers outside the UK. Researchers outside the original team would not be able to identify me from the information they get. _ _ _ _ Initials

7. I agree to a copy of this Consent Document being sent to the Clinical Trials Research Unit at the University of Leeds. _ _ _ _ Initials

8. I agree to share my bone marrow sample. _ _ _ _ Initials

Please indicate your wishes for if you are diagnosed with a related disease*, or myeloma but do not come to take part in iFIT:

Please <u>initial</u> under 'Yes' or 'No' for each statement

9. I give permission for the sample sent to the iFIT central laboratories to be stored and used in future research that receives ethical approval. I understand that the sample may be shared with researchers, possibly outside the UK.

YES	**NO**
_ _ _ _ Initials	_ _ _ _ Initials

**Other conditions related to myeloma known as 'plasma cell dyscrasias'. These conditions are called: Monoclonal Gammopathy of Undetermined Significance (MGUS), Smouldering Multiple Myeloma (SMM), Systemic Amyloidosis, POEMS syndrome and solitary plasmacytoma.*

Patient (to be completed by the patient):

Signature……

Name (block capitals)……

Date……

Investigator:

I have explained the request to the above named patient and they have indicated their willingness for their bone marrow sample to be sent to the iFIT laboratories.

Signature……..

Name (block capitals)……..

Date……

Witness:

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

Signature……..

Name (block capitals)……..

Date……

(1 copy for patient; 1 for the CTRU; 1 held in patient notes; original stored in Investigator Site File)