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

Participant ID:	Initials:
Date of Birth:	Principal Investigator:

MUK *nine a*

A phase II study identifying and evaluating high risk (HR) myeloma patients suitable for novel treatment approaches

SAMPLE PARTICIPANT CONSENT FORM

Participant initial after each statement

1. I confirm that I have read and understand the information sheet for the above trial and have had the opportunity to ask questions. .....

2. I understand that taking part in this trial is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above trial, the data and samples and MRI, CT scan and x-ray images collected from me will be used in analysing the results of the trial and in some cases further information about any unwanted effects of my treatment may need to be collected by the trial team. .....

3. I understand that my healthcare records may be looked at by authorised individuals from the trial team, the NHS Trust, regulatory bodies or Sponsor in order to check that the trial is being carried out correctly. .....

4. I agree to allow any information or results arising from this trial to be used for healthcare and/or further medical research upon the understanding that my identity will remain anonymous wherever possible. .....

5. I agree to a copy of this Consent Form, detailing my full name, being sent to the Clinical Trials Research Unit (CTRU) at the University of Leeds. .....

6. I agree that my GP, or any other doctor treating me, will be notified of my participation in this trial. .....

7. I agree that samples of blood, urine and bone marrow taken from me during the course of the trial may be used for additional research investigations that form part of this trial and that the samples will be sent to laboratories outside my hospital. .....

8. I understand that some of the research studies using my samples may include genetic research aimed at understanding the genetic influences on predicting response to treatments and predisposition to multiple myeloma, ...

but the results of these investigations are unlikely to have any implications for me personally.

9. I agree to take part in the trial. ……..

The following points are OPTIONAL. Even if you agree to take part in this trial, you do not have to agree to this part

Participant initial Yes or No

	Yes	No
1. If I am diagnosed with any disease other than symptomatic multiple myeloma or plasma cell leukaemia, I give permission to be contacted through my hospital about other research that may be available to me in the future	☐	☐

Consent for storage and use in possible future research projects

1. I agree that the samples I have given and anonymised information stored about me can be stored for possible use in future projects. I understand that some projects may be carried out by researchers at different institutions other than the trial team who ran the first trial. I understand that any future research using these samples would require further ethical approval.	☐	☐
2. I agree that information obtained through this research about the molecular features of my multiple myeloma or plasma cell leukaemia, e.g. findings about tumour mutations, may be fed back to my treating doctor if they are of potential relevance for my future treatment.	☐	☐
3. If I am diagnosed with any disease other than symptomatic multiple myeloma or plasma cell leukaemia, I give permission for the samples sent to the central laboratories to be stored and used in future research that receives ethical approval. I understand that the samples and data collected from them may be shared with researchers, possibly outside the European Economic Area (EEA).	☐	☐

Consent for the imaging study

My hospital is not taking part in the imaging study ☐

1. I agree to take part in the whole body MRI study.	☐	☐
2. I agree that the whole body MRI images I have given and anonymised information stored about me can be stored for possible use in future projects. I understand that some projects may be carried out by researchers at different institutions other than the trial team who ran the first trial. I understand that any future research using these scans would require further ethical approval.	☐	☐

Participant:

Signature…….

Name (block capitals)……

Date……

Investigator:

I have explained the trial to the above named participant and he/she has indicated his/her willingness to participate.

Signature……

Name (block capitals)……

Date……