



# ISCOMAT

Managing Medicines for Heart Failure Patients

|                            |                       |
|----------------------------|-----------------------|
| Participant ID:            | Participant Initials: |
| Participant Date of Birth: | NHS Number:           |
| Principal Investigator:    |                       |

## PARTICIPANT CONSENT FORM

|   |  | Please<br>initial<br>each box |
|---|--|-------------------------------|
| 1 | I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers provided.   |                               |
| 2 | I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.  |                               |
| 3 | I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the study.  |                               |
| 4 | I agree for my medical records (primary care, hospital, and community pharmacy records), including my electronic health records to be looked at by authorised individuals from the research team to obtain data on me.   |                               |
| 5 | I agree for my personal details (which will include my initials, date of birth, postcode, and NHS number) to be shared with providers of Electronic Health Records (including but not limited to NHS Digital, SystmOne, EMIS) so that information about my healthcare use can be obtained by the study team.   |                               |
| 6 | I understand that community pharmacies, participating in the study, from which I will collect my medication will provide information about me to the Clinical Trials Research Unit (CTRU) at the University of Leeds. I give permission for this to happen<br>(note, a copy of this consent form will be sent to the community pharmacy you use so they know you have consented to provision of this data) |                               |
| 7 | I understand that all data collected about me (including my name and contact details) will be kept confidentially and securely at the Clinical Trials Research Unit (University of Leeds).   |                               |

|    |  |  |
|----|--|--|
| 8  | I agree for my personal details (including name, date of birth, postcode, and NHS number) to be securely stored in accordance with the study sponsor guidance (up to 10 years).                                |  |
| 9  | I agree for access and use of data about me, as described above, to continue in the event of my death.   |  |
| 10 | I agree to a copy of this Consent Form being sent to the CTRU  |  |
| 11 | I agree that the research team will inform my GP that I am taking part in this study and will send them a copy of this completed consent form.   |  |
| 12 | I agree to allow any information or results arising from this study to be used for healthcare and/or further medical research upon the understanding that my identity will remain anonymous wherever possible. |  |
| 13 | I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly.          |  |
| 14 | I agree to take part in the study.   |  |

|                         |   |  |
|-------------------------|---|--|
| <b>Optional Consent</b> |   |  |
| 15                      | I agree, if selected, to be contacted by researchers in the study team from the University of Bradford to participate in extra interviews to give my feedback on my experience of taking part in the study. |  |
| 16                      | I agree to being contacted by text message with the understanding I may receive a text message reminder about the return of my questionnaire booklets after I have left hospital.                           |  |

**Patient:**

Your Signature.....

Your Name (block capitals).....

The date you signed this form (please write this yourself).....

**Section for Witness consent (if required):**

Your Signature.....

Your Name (block capitals).....

The date you signed this form.....



**Section for Research Nurse taking consent (to complete at the same time as the patient):**

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

Research Nurse Signature.....

Research Nurse Name (block capitals).....

Research Nurse Date of signature.....

**Instructions for Research Nurse:** Please create 1 copy for patient; 1 for the CTRU; 1 held in patient notes (original stored in Investigator Site File)

