RePROM Renal Electronic Patient Reported Outcome Measures

UNIVERSITY OF BIRMINGHAM

<insert local letterhead>

Informed Consent Form

Short Study Title: The RePROM Pilot Trial

Participant ID: R- ☐☐☐☐

Principal Investigator: _____

Please initial inside each box

1	I confirm I have read and understood the information sheet, dated _ _ / _ _ / _ _ _ _ version number __.__ for the **RePROM** study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.	☐
2	I understand that my participation 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. I understand that data collected up to my time of withdrawal may be used.	☐
3	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the **RePROM** research team, representatives of the sponsor, from regulatory authorities, or from the NHS Trust, where this is relevant to my taking part in this research. I give permission for these individuals to have direct access to my records.	☐
4	I agree to my GP being informed of my participation in this study.	☐
5	A copy of this consent form, which identifies me by name, will be transferred from University Hospitals Birmingham NHS Trust to the University of Birmingham, where it will be securely stored and used for study monitoring. I agree to the transfer, storage and use of this data.	☐
6	I understand that if the study research nurse becomes concerned for my wellbeing during a study review, they will discuss their concerns with me to determine the best course of action. With my permission, the research nurse may need to consult with a senior member of the study and/or my treating clinician to address these concerns. In exceptional circumstances, the research nurse may need to do this without my prior permission if they are concerned for my safety.	☐

7	I agree to take part in the **RePROM** study.	☐
8	**OPTIONAL** I am willing to take part in an interview at the end of the study to discuss my experiences. I understand that this interview will be audio-recorded and that the recording will be shared with researchers working on the **RePROM** study at University Hospitals Birmingham NHS Trust and the University of Birmingham. I understand that anonymised quotes from the interview may be included in arising research reports/publications. I understand that I may only withdraw from this aspect of the study within **5 working days** following the interview.	Please circle your response: **YES / NO** If you would like to take part in the interview, please initial in this box: ☐

Name of Participant	*Date*	*Signature*
Name of Person taking Consent	*Date*	*Signature*

When completed: give 1 copy to the participant, file 1 copy in the Investigator Site File, and file the original in the medical notes.