*[Print on Local Trust headed paper]*

# OPTIMA Qualitative Recruitment Study

## Consent Form - Audio-recording of consultations

| | |
|---|---|
| **Study Title:** | **O**ptimal **P**ersonalised **T**reatment of early breast cancer us**i**ng **M**ulti-parameter **A**nalysis: Qualitative Recruitment Study |
| **Study Number:** | ISRCTN42400492<br>IRAS ref. 95626 |
| **Study Doctor Name:** | |
| **Study Site:** | |

| **Patient statement and signature** | *Please **initial** boxes below if you agree* |
|---|---|
| 1. I have received and read a copy of the OPTIMA Qualitative Recruitment Study Patient Information Sheet (version 3.0, dated 8 November 2018). I fully understand what is involved in taking part and have had an opportunity to ask questions, and all of my questions have been answered. | |
| 2. I understand that my participation is entirely voluntary and that I am free to withdraw from the audio-recording study at any time without giving a reason and without my medical care or legal rights being affected. | |
| 3. I understand that my participation does not commit me to joining the OPTIMA study. | |
| 4. I understand that data collected for this study is covered by the Data Protection Act 2018 and all electronic data will be stored in a secure format. I understand that no information that allows me to be identified will be made public. | |
| 5. I give my permission for the OPTIMA Trial Office and other sites undertaking OPTIMA research to hold information about me for the purposes of my participation in audio-recordings. I understand that this will not include details of my identity. | |
| 6. I give permission for sections of my medical records to be looked at by the study team, the regulatory authorities or the hospital trust overseeing the research. I understand that strict confidentiality will be maintained. | |
| 7. I agree to data from my audio-recorded appointments being transferred to and retained by the University of Bristol for training, teaching and research purposes, now and in the future. I understand that anonymised quotes from interview transcripts may be used in publications arising from this research. | |
| 8. I voluntarily agree to participate in this study. | |

Your signature confirms that you have had an opportunity to ask questions and that all of your questions have been answered. [You will be given a signed and dated copy of this consent form to take away with you]

| Patient name (print): | Signature: | Date signed: |
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| _____ | _____ | _____ |

| **Investigator Statement and Signature**<br>***To be completed by the investigator or designee taking consent*** | | |
|---|---|---|
| I have discussed this clinical research study with the patient and/or his or her authorised representative using a language that is understandable and appropriate. I believe that I have fully informed the participant of the nature of this study and the possible benefits and risks of taking part. I believe the participant has understood this explanation. | | |
| Name (print):<br><br>_____ | Signature:<br><br>_____ | Date signed:<br><br>_____ |

The completed Consent Form must be kept in the OPTIMA site file, a copy given to the patient and copy filed in hospital notes.

Do not send the completed Consent Form to the OPTIMA Trial Office.