*[Print on Local Trust headed paper]*



Patient Consent Form - Audio-recording of consultations

OPTIMA Qualitative Recruitment Study

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| --- | --- | --- | --- | --- |
| **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  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 the OPTIMA Qualitative Recruitment Study Patient Information Sheet (version 4.1, dated 10 September 2020). I fully understand what is involved in taking part in this study. I have had an opportunity to ask questions and all of my questions have been answered. | | | |  | |
| 1. I understand that my participation does not commit me to joining the OPTIMA study. | | | |  | |
| 1. I understand that my participation is 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. I understand that withdrawal of data already used in reports and publications is not possible. | | | |  | |
| 1. I agree to audio-recordings of my consultations being transferred to and stored by the University of Bristol and their authorised representatives for research purposes and for training and teaching. I understand that anonymised quotes from consultation transcripts may be used in teaching and research activities. | | | |  | |
| 1. I agree to data from my audio-recorded discussions being made “Controlled Access” after the study ends. I understand this means data will be stored indefinitely and may be used for purposes not related to this study, but that it will not be possible to identify me from these data. | | | |  | |
| 1. I give my permission for the OPTIMA Trial Office and the University of Bristol to collect information about me for the purposes of my participation in audio-recordings. I understand that all information about me will be stored securely and will only be accessible by authorised personnel. | | | |  | |
| 1. I voluntarily agree to take part in this study. | | | |  | |
| [You will be given a copy of the completed consent form for your records.] | | | | |
| Patient name (print):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date signed:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **Investigator Statement and Signature**  ***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 patient of the nature of this study and the possible benefits and risks of taking part. I believe the patient has understood this explanation. | | | |
| Name (print):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date signed:\*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

\* Where the investigator or designee is countersigning a consent form returned by post or electronically, the ‘Date signed’ may be different to the patient’s ‘Date signed’

The original Consent Form must be retained on site and should be stored in the trial site file with a copy filed in the patient’s hospital notes.

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