*(Form to be on headed paper and/or use local NHS Trust logo)*

IRAS ID:

R&D study reference number:

Participant Identification Number for this study:

**CONSENT FORM**

Short title of study:

Full title of study:

Name of Principal Investigator:

 Please initial box

**PLEASE TURN OVER**

|  |  |
| --- | --- |
| 1. I confirm that I have read the information sheet (dated.................... version number..........) for the above study.
 |  |
| 1. I have had the opportunity to consider the information, ask questions about the study and received satisfactory answers to my questions.
 |  |
| 1. 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.
 |  |
| 1. I understand that relevant sections of my medical notes and data collected about me during the study may be looked at by individuals from the University Hospitals Bristol and Weston NHS Foundation Trust (sponsor), the study team, regulatory authorities and the treating NHS Trust, where it is relevant to my taking part in this research, for the purposes of managing, monitoring and auditing the study. I give permission for these individuals to have access to my records.
 |  |
| 1. I give permission for information collected about me by the local research team, including information which may identify me, to be shared with the *[short title of study]* study team at *[employing organisation of study team]* for the purpose of managing and monitoring the study.
 |  |
| 1. I understand that strict confidentiality will be maintained when handling my personal data and that arrangements for managing my personal data are set out in the information sheet.
 |  |
| 1. *[If applicable]* I agree for my samples to be collected for the purposes of this study, as described in the Patient Information Sheet.
 |  |
| 1. *[If applicable]* I agree for my anonymised quotes to be included in research papers and publications.
 |  |
| 1. *[If applicable]* I understand that my *[insert a brief description of data/images/samples]* will be shared with other organisations for the purposes of the study and that I cannot be identified from them.
 |  |
| 1. *[If applicable]* I give permission for the local research team and the [short study title] study team to share [list types of personal details, including any special category data] with *[name of third party/ies]* for the purposes of *[identify types of activities]*.
 |  |
| 1. *[If applicable]* I understand that [name of organisation] may obtain information held and maintained by *[enter name of organisation(s) that will be providing the data, including any NHS/HSC organisations]* and that this information may be used to help contact me or provide information about my health status.
 |  |
| 1. *[If applicable]* I give permission for my personal data collected for the purposes of the study to be *[transferred/stored]* outside the UK. I understand that some countries may have different data protection governance requirements from the UK. (*[enter name of organisation]* receiving your personal data will not be able to identify you.)
 |  |
| 1. *[If applicable]* I give permission for my samples to be transferred outside the UK for processing for the purposes of this study. (Organisations receiving your samples will not be able to identify you.)
 |  |
| 1. I give permission for information collected about me to be used to support future research and shared with other researchers. I understand that I cannot be identified from this information.
 |  |
| 1. *[If applicable]* I agree to my GP being informed of my participation in this study, including any necessary exchange of information about me between my GP and the study team.
 |  |
| 1. *[If applicable]* I give permission for audio/video recordings to be taken.
 |  |
| 1. I agree to take part in the above study.
 |  |

**Optional section**

**The following is optional. Answering "No" will not affect your ability to participate in the study. Please tick ‘yes’ or ‘no’ and initial.**

**PLEASE TURN OVER**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No |  Initial |
| 1. *[Include if samples being collected are for future research only]*. I agree to samples being taken from me on the study visits described in the information sheet so that material taken from my samples, including *[list any HTA licensed material eg serum and DNA]* can be stored for future research, including genetic studies.
 |  |  |  |
| 1. *[Include if samples being collected are for the purposes of the study and for future research]*. I donate *[samples/images]* collected from me as part of the study as a gift which may be used for future research, including genetic studies.
 |  |  |  |
| 1. I give permission for any unused or leftover samples to be stored indefinitely in a tissue bank for future research in the UK or abroad and for the tissue bank to receive and retain a copy of my consent form.
 |  |  |  |

**Signatures:**

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_

Name of Participant Date (MM/DD/YYYY) Signature

(Print)

**To be completed by a delegated member of the local research team obtaining consent:**

 \_\_\_ \_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Date (MM/DD/YYYY) Signature