***PLEASE NOTE THAT THIS IS A TEMPLATE THEREFORE IT WILL NEED TAILORING TO MEET YOUR STUDY REQUIREMENTS IN A STYLE SUITABLE FOR THE TARGET AUDIENCE.***

***PLEASE ENSURE THAT ALL ELEMENTS OF YOUR CONSENT FORM ARE COVERED IN THE PARTICIPATION INFORMATION SHEET.***

***SECTION A – This section requires the participant consent to carry out the research (mandatory).***

***SECTION B - The statements in this section are optional. The consent for these statements are not mandatory for the participant to be able to take part in the study. - DELETE IF YOU DON`T NEED***

***DELETE THIS HEADER ONCE READY FOR SUBMISSION*.**

REC Reference Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IRAS ID: ***(DELETE IF YOU DON`T NEED)***

Participant`s Identification Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CONSENT FORM**

**Title:** *Please insert SHORT OR LONG study title*

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Participation Information Sheet or explanation already given to you, please ask the researcher before you decide whether to participate. You will be given a copy of this Consent Form to keep and refer to at any time.

|  |
| --- |
| ***Section A – This section requires your consent for us to carry out the research with you. By initialling each box, you are consenting to this element of the study. It will be assumed that un-initialled boxes mean that you DO NOT consent to that part of the study and you may be deemed ineligible for the study.*** |
| **Name of Researcher:** *Please insert researcher name* **Please** **initial** |
| I confirm that I have read and understood the participant information sheet dated ***[INSERT DATE AND VERSION NUMBER]*** for the above study. I have had the opportunity to consider the information and ask questions which have been answered satisfactorily. |  |
| I understand that my participation is voluntary and that I am free to withdraw at any time during the study without giving any reason and without being disadvantaged in any way. Furthermore, I understand that I will be able to withdraw my data up to ***[INSERT DATE STATED ON PARTICIPATION INFORMATION SHEET, or INSERT TEXT CLEARLY DEFINING TIME LIMIT E.G. ONE MONTH AFTER THE INTERVIEW] OR [I UNDERSTAND THAT IF I WITHDRAW FROM THE STUDY IT MAY NOT BE POSSIBLE TO REMOVE THE DATA I PROVIDED ONCE MY PERSONAL INFORMATION IS NO LONGER LINKED TO THE DATA].***  |  |
| I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with current data protection regulations. |  |
| I understand that my information may be subject to review by responsible individuals from the sponsor and/or regulators for monitoring and audit purposes. |  |
| I understand that I am agreeing to take part in the interview or discussion group(s) or focus group(s) for the purposes set out in the participation information sheet and I understand that these will be recorded using electronic audio or video recording equipment. I understand the transcript will be available upon request. ***[AMEND ACCORDING TO YOUR RESEARCH INTERVIEW OR FOCUS GROUP, DELETE IF YOU DON`T HAVE RECORDING]*** |  |
| I agree to my samples being used as described in the participation information sheet ***[DELETE IF YOU DON`T COLLECT SAMPLES]*** |  |
| **Name of Participant:** **Date:** **Signature:**  |
| **Name of Person taking consent:** **Date:****Signature:** |

***FOR ANY OPTIONAL STATEMENTS, ADD SECTION B BEFORE THE SIGNATURES.***

|  |
| --- |
| ***Section B – The following statements are optional. Please only put your initial in the boxes next to the statements you wish to consent to. The consent for these statements are not mandatory for you to be able to take part in the study.*** |
| **Name of Researcher:** Please insert researcher name **Please** **initial** |
| …………. |  |

***PLEASE ADD ANY OF THE RELEVANT STATEMENTS BELOW INTO THE CORRECT SECTION BEFORE THE SIGNATURES, OR OTHERWISE DELETE.***

***STATEMENTS FOR FOCUS GROUP/DISCUSSIONS***

|  |  |
| --- | --- |
| I understand that I may be quoted directly in the reports of the research but I will not be directly identified (i.e. that my name will not be used). ***SECTION A*** |  |
| I understand my anonymity and confidentiality cannot be guaranteed in a focus group but any information collected by the researchers will be kept confidential.***SECTION A*** |  |
| I understand that I must keep the discussions confidential. ***SECTION A*** |  |

***STATEMENTS FOR FURTHER RESEARCH***

|  |  |
| --- | --- |
| I agree to be contacted in the future by the Sponsor`s researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ***SECTION B*** |  |
| I agree that the research team may use my data for future research and understand that any use of identifiable data would be reviewed and approved by a research ethics committee. In such cases, as with this project, data would not be identifiable in any report. ***SECTION B*** |  |
| I agree to my samples being used for future research studies. ***SECTION B*** |  |

***STATEMENTS FOR MEDICAL RESEARCH***

|  |  |
| --- | --- |
| I agree that my GP may be contacted if any unexpected results are found in relation to my health. I will be informed when this happens. ***SECTION B*** |  |
| I agree that the research team may access my academic/membership/ medical records for the purposes of this research project. ***SECTION B*** |  |
| I understand that my ***[INSERT THE TYPE OF SAMPLE: BLOOD, URINE ETC]*** samples collected for this study may be stored in a Human Tissue Authority licenced tissue bank for…. years. It will only be used in future ethically-approved research studies. ***SECTION B*** |  |
| I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from St George’s University of London (SGUL) and/or St George’s University Hospitals NHS Foundation Trust (SGHT), the NHS Trust or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ***SECTION A*** |  |
| I agree to my samples being used for future research studies. ***SECTION B*** |  |

***STATEMENTS FOR ACCESS TO DATA***

|  |  |
| --- | --- |
| I agree that my GP may be contacted if any unexpected results are found in relation to my health. I will be informed when this happens. ***SECTION A*** |  |
| I agree that the research team may access my academic/membership/ medical records for the purposes of this research project. ***SECTION B*** |  |
| I consent for my data to be sent to (specify institution outside of EU) where the same data protection controls might not be in place. ***SECTION A*** |  |