GUIDANCE

This Consent Form Template is intended as a suggestion for the layout to be used for Global Health research studies that are taking place outside of the UK and which are sponsored by The University of Edinburgh.

For some studies it may be appropriate to provide itemised consent covering specific issues. Only offer potential participants options if you are confident that you can deliver all combinations of accepted or rejected options.

Guidance is provided in *italic* in blue below. Please removal this guidance when finalising this document.

Text in black should remain unchanged.

CONSENT FORM

*Insert study title*

**Purpose of study: Insert a sentence/short paragraph to summarise the study.**

|  | Please **initial** box |
| --- | --- |
| 1. I confirm that I have read and understand the information sheet (DD MMM YYYY and Version Number) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.
 | c |
| 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 and/or legal rights being affected.
 | c |
| 1. I give permission for the research team to access my medical records for the purposes of this research study **(delete row if not relevant)**
 | c |
| 1. I understand that data collected about me during the study may be converted to de-identified data.
 | c |
| 1. I understand that data generated during the study will be sent outside of my home country to the United Kingdom, where laws protecting my personal information may be different to my own country.
 | c |
| 1. I agree to give a blood sample which will be used for genetic DNA analysis **(delete row If not relevant)**
 | Yes c No c |
| 1. I give permission for whole genome/exome analysis to be conducted on my sample **(delete row If not relevant)**
 | Yes c No c |
| 1. I agree to my identifiable data and/or tissue being used for future ethically approved studies **(delete row If not relevant)**
 | Yes c No c |
| 1. I agree to my de-identified data and/or tissue being used in future studies **(delete row If not relevant)**
 | Yes c No c |
| 1. I agree to my interview being audio/video recorded **(delete row If not relevant)**
 | Yes c No c |
| 1. I agree to my audio/video recorded interview being transcribed by <insert details of person/organisation responsible for transcription> **(delete row If not relevant)**
 | Yes c No c |
| 1. I agree to my tissue being used in procedures involving animal **(delete row If not relevant)**
 | Yes c No c |
| 1. I agree to my tissue being used to create stem cells **(delete row If not relevant)**
 | Yes c No c |
| 1. I understand that the data generated and tissue collected during this study may be used for future commercial development of products/tests/treatments/biomarkers and I will not benefit financially from this **(delete row If not relevant)**
 | c |
| 1. I understand that if I have concerns about this research, I can contact the Principal Investigator.
 | c |
| 1. By signing this form, I give my free and informed consent to take part in this study as outlined in the Participant Information Sheet and Consent Form.
 | c |

|  |
| --- |
| **Name of Participant:** Signature/ Thumb Impression\*: Date (DD/MM/YYYY):*\*Thumb impression to be used if participant is illiterate* |
| **Name of Person Obtaining Consent:**Signature: Date (DD/MM/YYYY): |
| **Name of Witness:** Signed by impartial literate third party witness (*In case of illiterate Participant/ Legally Authorized Representative is illiterate*)Signature:  Date: Place of signature: |

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record (if applicable)