NOTE TO RESEARCHERS: Please delete/add points to match your protocol before submitting this form. Participants should be consenting to one point at a time for transparency and to ensure there is no misunderstanding or inadvertent omission on their part.

(...) Sentences that may be particularly study specific and optional. Insert the wording relevant to your study.

* Delete an option as appropriate.

It should be made clear in the participant information sheet which elements of the study are compulsory and which, if any, are optional. Alternatively, you may list all optional statements under an 'optional' heading.

Consent Form [version x, date dd/mm/yy] {participant type/group}

[study title] {{study reference number(s)}}

Please initial each box

- I have read and understood the Information Sheet provided (version x, date dd/mm/yy). I have been given a full explanation by the investigators of the nature, purpose, location and likely duration of the study, and of what I will be expected to do.

- I have been advised about any disadvantages/risks/discomfort/possible ill-effects* on my health and well-being which may result. I have been given the opportunity to ask questions on all aspects of the study and have understood the advice and information given as a result.

- I agree to comply with the requirements of the study as outlined to me to the best of my abilities. {I shall inform the investigators immediately if I have any concerns / suffer any deterioration of any kind in my health or well-being / experience any unexpected or unusual symptoms*}.

- {I understand that in accordance with the English law, insurance is in place which covers harm that is likely to result from my participation in this study as detailed in the participant information sheet}

- I agree for my {anonymised} data and/or* samples to be used for this study / future research that will have received all relevant legal, professional and ethical approvals*.

- {I give consent to [aspect of the research] to be audio recorded}

- {I give consent to [aspect of the research] to be video recorded}

- {I give consent to {anonymous} verbatim quotation/photographs/audio recordings/videos* being used in reports]

- I understand that all project data will be held for at least 6 years and all research data for at least 10 years in accordance with University policy [adjust if required longer by clinical trials regulations, funder etc.] and that my personal data is held and processed in the strictest confidence, and in accordance with the {UK} Data Protection Act (1998).

- {I agree to the investigators contacting my general practitioner about my participation in the study. [Only legally required for Phase I trials and where the subject’s health & medical record is relevant.]}

When completed: 1 for participant; 1 for researcher site file (; 1 (original) to be kept in medical notes).
• {I authorise my GP to disclose details of my relevant medical or drug history, in confidence.}

• {I agree for the researchers to contact me to provide me with updates about my health status.}

• {I agree for the researchers to contact me to provide me with updates about my medical results.}

• {I agree for the researchers to contact me to provide me with a study results summary.}

• {I agree for the researchers to contact me about future studies.}

• I understand that {relevant sections of my medical notes and} all data collected during the study, may be looked at for monitoring and auditing purposes by authorised individuals from [company name, University, government, pharma, other], from regulatory authorities [or from the NHS Trust], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

• {I agree for my anonymised data and/or samples* to be shared with [advised to specify third party]}

• {I agree for my personal data and/or identifiable samples* to be transferred to [compulsory to specify third party outside research team] Sharing of personal data is not recommended and should ideally be optional [if outside EU: I understand that my personal data may not be held under the same stringent laws as in the UK].}

• I understand that I am free to withdraw from the study at any time without needing to justify my decision, without prejudice and without my legal rights and studies/employment/medical care* being affected.

• I understand that I can request for my data to be withdrawn until [date/e.g. submission of online questionnaire] / until publication of the data* and that following my request all data already collected from me will be destroyed/ personal data will be destroyed but I allow the researchers to use anonymous data already collected/ I allow the researchers to use anonymous data already collected*.

• {If I withdraw I also allow the researchers to use my personal data, in addition to anonymous data, already collected as outlined in the participant information sheet and this consent form}

• {I acknowledge that in consideration for completing the study I shall receive compensation for my time and inconvenience and I recognise that the sum would be less [amount if known/as per the participant information sheet / at the discretion of the Principal Investigator*], if I withdraw before completion of the study.}

• I confirm that I have read and understood the above and freely consent to participating in this study. I have been given adequate time to consider my participation.

Name of participant (BLOCK CAPITALS) .................................................................

Signed ........................................................................................................

Date ...........................................................................................................