***[NOTE: the exact formulation of the consent documentation should be adjusted to the organisation leading the study, and the text must be approved by the organisation’s ethics review board before use, according to local policies and regulations.]***

[*Form to be on headed paper of iPSC Centre including clearly stated name of study and document version number and date*]

**Name of Centre:** *[Center name]*

**Name of Study:** *[Study name]*

**Document version / date:** *[Document version and date]*

**Project: [iPSC project initiated by the iPSC Centre ]**

**CONSENT**

**If you agree, please initial box**

|  |  |
| --- | --- |
| 1. I confirm that I have read, considered, and understood the [*iPSC Centre Project*] Information Sheet, version [ # ], dated [*day/month/year*] and the [*EBiSC/iPSC Centre*] Information Leaflet, version [ *#* ], dated [*day / month / year*]. |  |
| 1. I have had the opportunity to ask questions, and have had them answered to my satisfaction. |  |
| 1. My donation is voluntarily given. |  |
| 1. I understand and agree that material and information derived from the samples I donate may be stored indefinitely, and made available to researchers around the world. |  |
| 1. I agree that DNA, full genome sequencing data, and other genetic information originating in the samples I donate may be collected, stored and made available to researchers. |  |
| 1. I understand that by generating, using and sharing genetic information from my donated sample, there is a very small risk that I could be identified and that [*name of iPSC centre*] will abide by all local regulations and policies to prevent this as much as possible. |  |
| 1. I give permission for health professionals to make relevant portions of my medical records available to researchers. |  |
| 1. I understand that any samples I donate, and material and information derived from them, may be used in future research, without any need for further consent by me. |  |
| 1. I understand that any samples I donate, and material and information derived from them, may be used in a commercial context and that I have no rights to any gain or benefit from this use. |  |
| 1. I understand that I will receive no financial gain, research results, health benefit, or any other immediate benefit, as a consequence of my donation of tissue. |  |
| 1. I understand that unless required by national law, no information gained from tests conducted on the donated samples, or on iPS cells derived from them, will be communicated to me. |  |
| 1. I understand that I am free to withdraw from the project at any time, and that withdrawal means: 2. any iPS cells that have already been created and from the donated samples and distributed will not be destroyed, and anonymised information about them will be retained; 3. any original donated samples that are stored, or any portion of them that has not been consumed, will be returned or destroyed at my request; 4. information that I have provided, or that with my consent has been obtained from my medical records, will be deleted and not used for research or any other purpose; 5. I retract my consent to any future access to my medical records*.* |  |
| 1. In the case that I withdraw my consent from the project, I specifically retract my consent to ongoing sharing of any -omic or genetic data, which was generated in the project. |  |
| 1. I agree to give samples of my [*name specific tissue type*] to [*name of* *iPSC Centre*]. |  |
| 1. I exercise my “right not to know” about incidental findings that may have a significant impact on my health. |  |
| 1. I [*am / am not*] willing to be re-contacted at any time in the future in connection with this or any other such project. |  |

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**Name of Participant Signature Date**

I confirm that the purpose of the project and the voluntary nature of the donation have been explained in terms understandable to the participant.

**---------------------------------- ------------------------------ -----------------------**

**Name of person taking consent Signature Date**