**[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]**

**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 ]*

**PARTICIPANT INFORMATION LEAFLET** *[version # / date]*

## PART 1

## Welcome

*[iPSC Centre to introduce project: recommended text below]*

We would like to invite you to contribute to a project involving the creation of induced pluripotent stem (iPS) cells for biomedical research. This work requires a variety of participants to provide samples of tissue or cells, such as [*add/delete as appropriate: blood, skin or urine*], from which these iPS cells can be generated. Before you decide to contribute, you should understand why your donation is being requested, and what it will involve.

Please read this leaflet carefully and, if you wish, discuss it with others. Part 1 describes the project’s purpose and what will happen if you decide to donate. Part 2 gives you more detailed information about how the project will operate. Your participation is entirely voluntary, and your decision will not affect your present or future medical care. Please ask if anything is unclear or you would like more information. Thank you for considering this invitation.

1. **Induced Pluripotent Stem Cells**

**What are they?**

An iPS cell is a type of *‘pluripotent’* stem cell, which means that it can grow into the most specialised cell types in the human body, such as muscle, nerve, germ or liver cells. iPS cells are generated from samples of adult tissue such as blood, skin or hair, and ‘induced’ in the laboratory to be pluripotent. They differ from embryonic stem cells, which are naturally pluripotent and can only be derived from an early-stage developing embryo. IPS cells can be cultivated to form a group of cells called an ‘iPS cell line’ or ‘iPSC line’, which may survive indefinitely.

Human iPS cells are useful *research tools*, especially for studying the effect of genes on disease risks and for the development of new drugs and methods. Research using iPS cells could lay the groundwork for future cell therapies in the regenerative medicine field. All the work must be carried out according to strict regulations and guidelines.

**How will they be used?**

*[Text to inform the tissue provider (donor) that donation supports research use and that research includes the development of commercial products; neither donated tissue nor iPS cells generated from it are for clinical application]*

The iPS cells generated from the samples you donate will only be used for *research*. Any research involving the samples that you donate, and any cells or information generated from them, will:

* comply with all relevant legal rules and regulations; and
* be approved as necessary by a research ethics committee, following the requirements of any relevant competent authority.

The samples you donate may be used in connection with future research, without any communication with you about the nature of that research, or to obtain any further consent from you. Future research includes anticipated projects that are not yet specifically defined, as well as research agendas that may at present be completely unforeseeable.

The results of iPSC research involving the samples you donate may include not only new data, information and knowledge, but new technologies, patentable research methods and tools, and commercial products.

1. **Why have I been chosen?**

You have been approached because you have particular genetic or other characteristics that may be of interest to researchers. Your donation will contribute to a collection of iPS cell lines, representative of a wide range of types of patients, which will be made available for study by researchers.

1. **What would I have to do?**

*[Adapt to specify local clinic and relevant procedures]*

If you are interested in contributing to this project, you will be asked to visit the [*clinic*]***,*** at your convenience. You will be asked to provide some general information about your health and, if you are a suitable candidate, to donate samples of tissue, which might be [*amend as needed: blood, urine, a small piece of skin, or other tissue*].

If you decide to take part, you will be asked to sign a Consent form. You will be given copies of this Information Sheet and the Consent form to keep.

1. **Are there any risks?**

*[Further detail may be added if required for alternative tissue types]*

The standard technique for taking blood will be used. You may have some minor discomfort; some people experience brief dizziness, and more rarely bruising at the site of needle entry. Infection or nerve damage in the area of the needle insertion is very rare.

The skin biopsy procedure, involving removal, under local anaesthetic, of a small (3 mm diameter) piece of skin tissue does not generally require a surgical suture (or stitch) and is regarded as having an extremely low risk of complication. Infection at the biopsy site is very rare.

1. **Will I receive any benefits?**

*[Text must ensure that the donor does not expect any sort of immediate benefit]*

No. Your donation will be a gift, and you will not be paid any money, except possible compensation for expenses, for your contribution. When you donate tissue, you are giving up all your rights to the donated material and to any iPS cells that may be produced from it, which will be the property of the iPSC Centre that generated them.

This means that you will have no right to restrict the development work that is carried out in connection with your samples, nor will donation give you any rights about discoveries or inventions that may result from it. You will not receive any financial gain or commercial benefit from your donation, even if the donated samples are used in the development of products that are patentable or commercially profitable.

The results of any research involving the donated tissue, or iPS cells made from it, will be published in research journals from which researchers worldwide will benefit.

It will take a long time to develop safe, effective drugs or treatments based on research using iPS cells, and you should not expect to receive any immediate healthcare benefits, such as new drug treatments or therapies because of your donation. Your participation will help medical research to better understand diseases and develop better treatments for them, which may help you, your family, or others in the future.

1. **Can I change my mind about the donation?**

*[Due to the nature of iPSC research, the opportunity for withdrawal of the tissue provider (donor) is limited regarding the destruction of iPS cells or information generated from them]*

Yes, you can choose to stop your involvement in the project at any point, but once iPS cells have been made, the iPS cells will not be destroyed, and they may continue to be used in the development of new drugs and treatments Once they have been distributed to others they will not be retrievable. There is only a short period, after your tissue has been collected, and before it is anonymised, when all of your original samples can be withdrawn.

1. **What happens if I withdraw my consent from the project?**

*[The third bullet can be adapted, and the fourth deleted, if ongoing access to medical records does not receive local approval]*

Withdrawing your consent from the project, at any time, means that:

* any iPS cells that may have been created from the donated samples, including iPS cells that have already been distributed, will *not* be destroyed, and anonymised information that has been generated about them will be retained;
* any remaining original samples that are stored, or have not been consumed, will be returned or destroyed, at your request;
* any personally identifying information about you or your medical history that you have provided, or that has been obtained, with your consent, from your medical records, will be deleted and will not be accessible for use in research or for any other purpose;
* your consent to provide ongoing access to your medical records is retracted, and no further information will be obtained from your medical records;
* any iPS cell lines made from the samples you donated will be decoded to remove any link between the iPS cells and your personal information to ensure, as far as possible, your anonymity.
* basic demographic data about you and your cells, which is not personally identifying (e.g. disease status, age (in 5-year brackets), genetic sex), will be retained.
* -omic or genetic data associated with the participant biomaterial (which is personally identifying), which was created in the study and whose access is determined by a Data Access Committee, will remain available via controlled access, for health research, unless specifically revoked in the consent form. Some -omic or genetic data may already have been distributed before consent withdrawal, and this data cannot be retrieved.

**If this information has interested you and you are thinking about taking part, please read the additional information in Part 2 before making any decision.**

**PART 2**

1. **What will happen to the tissue I donate?**

*[Further detail could be provided locally, if necessary]*

The samples you donate will be transported to [*iPSC Centre*], where the tissue will be prepared for culturing. All work involving your donated samples must comply in every way with all applicable laws, regulations and policies. Cells from the samples will be stored in the laboratory and may be used:

* to test for specific infectious agents, including HIV;
* to create cell lines, which provide a renewable source of cells;
* to provide DNA, enabling identification of specific disease-associated gene sequences or collection of genetic data;
* to grow cell cultures designed for ‘reprogramming’ into iPS cells;
* to derive other cells from them, which may be genetically modified;
* in research methods using animal models
* to perform or develop as yet unknown research;

A sample of the iPS cells generated from donated tissue will typically be transferred to the European Bank for induced Pluripotent Stem Cells for safeguarding and distribution. To ensure user safety, further tests for infectious agents may be conducted on the iPS cell lines after shipping. IPS cell lines can be kept alive indefinitely, which means that the cells may be used for research for many years to come.

**What is the European Bank for induced Pluripotent Stem Cells (EBiSC)?**

*[Essential information about EBiSC]*

EBiSC is a not-for-profit ‘stem cell bank’, which hosts a diverse collection of iPS cell lines, in a centralised facility, to make them easily available to researchers in Europe and around the world. An EBiSC ‘mirror bank’ stores copies of all EBiSC iPSC lines to ensure a backup is available in case of unforeseen events impacting the main facility. EBiSC iPSC lines are listed anonymously on a public catalogue and more information is available at www.EBiSC.org.

EBiSC provides a significant biomaterial resource for researchers, who are increasingly looking to use iPS cell lines to help understand disease, to develop new drugs and find new methods for creating therapies that might in future replace or treat damaged and diseased tissue.

EBiSC supports many different research projects, most of which are not yet defined, over an indefinite period. It has the potential to generate long-term public health benefits and increase social well-being.

Now established, the Bank operates independently, on a non-profit basis. It will continue to rely on the voluntary contribution of iPS cell lines, facilities and expertise from iPSC researchers across Europe. It will also charge a reasonable fee to users who obtain iPS cell lines from the Bank to cover not-for-profit operations.

1. **Who might use my cells?**

*[Donor must be aware of the lack of foreseeability of future iPSC research]*

At the time of your donation, no one can foresee precisely who will use the iPS cells made from the samples you donate.

Patients, medical research and society benefit from the sharing of cells, and information about them, among clinicians, researchers and institutions. What we know is that the EBiSC Bank will make iPS cells available to clinicians and researchers at hospitals, universities, private corporations such as pharmaceutical companies and small and medium-sized enterprises (SMEs), and other institutions internationally for the development of new drugs and treatments.

Investigators from all around the world may obtain iPS cell lines (and associated information and data) derived from the samples you donate.

1. **What type of information will I be asked to provide?**

*[Subject to local approval]*

With your consent, several types of data and information may be collected from you, from the samples you donate, from iPS cells made from them, and from your medical records.

* Genetic information. Your DNA sequence, and other genetic information, may be collected by an iPSC Centre or EBiSC. You may be asked to confirm if you are aware you are carrying any genetic variants associated with a known disease.
* Clinical information. You will be asked at the time of your donation to provide information about your health and any medical conditions you may have.
* Medical records. You will also be asked to give permission for researchers to look at your medical records at regular intervals in the future.

The accumulation of information associated with the donated samples creates a valuable resource for research, particularly for scientists studying the effect of genes on disease. The information will be stored indefinitely in databases and shared with other researchers to help them with their scientific research.

1. **How will my privacy be protected?**

*[More detail may be added to describe specific procedures, and the parties who will assign codes, hold keys, and provide access, as necessary in the local jurisdiction]*

All information that is collected will remain strictly confidential. To ensure that confidentiality is maintained:

* a code will be allocated to your samples and records;
* your personal details will be kept separate from samples and information but linked by that code. This process is known as pseudonymisation. The keys that link you with the samples and information will be held securely by [iPS Centre or other body];
* researchers will only have access to the code (or pseudonym), not your personal details;
* by using codes to identify the tissue providers, you are essentially anonymous to the researchers.
* As an extra security measure, [iPS centre or other body] may “throw away the key”, such that the link between you and the samples and data is broken. In such cases, your data becomes anonymised at the source institution.
* all information will be held in secure databases, in conformity with current best practices;
* reports or publications of research findings will also be encoded to avoid situations in which your identity may be revealed.
* Insurance companies and employers will not have access to any information held about you. Access by the police will not be granted, other than under court order. It is not possible however to guarantee that your identity will not be traceable through other public data systems.

*[If study Participants are being identified and recruited in the European Union, suitable guidance on the General Data Protection Regulation 2018 should be included. Suggested text is included here, it is strongly recommended to check your local jurisdiction for policies and guidance]*

[*Sponsor organisation*] is the sponsor for this study based in [*the United Kingdom/ country*]. We will be using information from [*you and/or your medical records*] to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. [*Sponsor organisation*] will keep identifiable information about you [*for x years after the study has finished/ until yyyy-mm-dd*].

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information [*at URL and/or by contacting XXX*].

[*Sponsor organisation*] will collect information about you for [*research/ this research study*] from [*source*]. [*Source*] will not provide any identifying information about you to [*sponsor organisation]*. We will use this information to [*purpose*]. If you have any questions or concerns about data protection, you may contact the Data Protection Officer of [*Sponsor organisation*]: [*Name of DPO*]; Address: [Address]; Telephone: [Telephone no.]; E-mail: [email].

When you agree to take part in this research study, the information about your health and care may be provided to researchers running other research studies in this organisation and other organisations. These organisations may be universities, hospital organisations or companies involved in health and care research in this country or abroad.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for health and care research. It will not be used to make decisions about future services available to you, such as insurance.

1. **Will incidental findings be communicated back to me?**

During this study, your donated tissues or cells will be tested for infectious agents such as HIV and others, for the safety of lab personnel who will be handling the cells. Furthermore, researchers may perform analyses on the cells, such as genomic sequencing, which may reveal risk factors for certain diseases. If your data has been anonymised in this study, incidental findings will not be communicated back to you, as the link to you has been severed. If your data has been pseudonymised, the clinical contact of the study may still have the means to contact you. In such cases, significant actionable incidental findings found in the course of this study or found by researchers working with your cell lines or data, may be communicated back to the clinical contact of this study, and in turn, to you, if there could be a significant impact on your health. You also have the “right not to know”.

## Further information

## *[Details to be provided at the local level]*

## In this leaflet, we have tried to answer any questions you may have about the [*iPSC Centre*]project and EBiSC. If you have any further questions, please speak to [ xxx ] for additional explanation. If after speaking with them you still have queries, please contact [*Name*] who is completely independent of this project:

Name:

Address:

Tel.

If you have any concerns or complaints arising from this project, please contact:

Name:

Address:

Tel.