**GSCN sample document**

**Information on and informed consent for the use of somatic cells and related data for the creation of human induced pluripotent stem (hiPS) cells for medical research purposes[[1]](#footnote-2)**

*Based on the International Society for Stem Cell Research (ISSCR) “Sample Research Consent Form on Somatic Cell Donation for Induced Pluripotent Stem Cell Research” in Appendix 2.2 of the ISSCR Guidelines for Stem Cell Research and Clinical Translation dated May 12, 2016 and the “Template for informed consent concerning the utilization of biological materials and related data in biobanks” recommended by the Permanent Working Party of the German Medical Ethics Committees (version 2.0, in accordance with the resolution of June 10, 2016).*

*This sample document may not conform to the standards of your local human subjects review committee and may need to be amended.*

(As at: April 25, 2018)

**Patient/participant details (adult)**

**Project title:**

**Principal Investigator:** [Name and address]

**Participating Institution(s):** [Name(s) and address(es)]

1. **PROJECT INFORMATION**

Dear patient/participant,

Human stem cells are an important tool for medical research. **You are therefore being asked to donate specific biological materials and data for medical research purposes.** You are being asked to donate *[insert biological materials]*[[2]](#footnote-3) to create stem cells for a research project. This research project will be carried out by *[name of principal investigator]* at *[name(s) of institution(s)]*. You are being invited to participate in this project because *[identify medical or other reason for inclusion]*. The purpose of this project is to create stem cells that have *[identify characteristics]*.

Powerful stem cells can be created (or “induced”) by changing normal cells from your body, such as skin cells or blood cells, into pluripotent cells in a laboratory. “Pluripotent” means that the cells can turn into any kind of cells such as brain, heart, or kidney cells. For this reason, induced pluripotent stem cells can be used to study, and maybe one day help treat, diseases or injuries that cause patients’ cells to die or become damaged.

*[Name of principal investigator]*wants to create induced pluripotent stem cells using your donated *[insert biological materials]*. ***[Insert additional information about this specific project using very simple, generally comprehensible language.]***

The *[insert biological materials]* and stem cells created from them will be linked to related data. We explain in more detail what this data is in section 4, “HOW WILL MY *[insert biological materials]* BE COLLECTED AND WHAT DATA WILL BE COLLECTED?”

1. **VOLUNTARY CHOICE**

**Donating your *[insert biological materials]* for this research project is completely voluntary.** You have the right to agree or to refuse to provide your *[insert biological materials]* for this project. **The quality of your current or future medical care and your relationship with *[name(s) of institution(s)]* will not change in any way whether you agree or refuse to provide any cells for this research project.**

1. **WHAT IS THE PURPOSE OF THIS INFORMATION SHEET AND CONSENT FORM?**

*[Name of person obtaining consent]* will give you information and answer your questions about this research project. It is very important that you have a detailed conversation with *[name of person obtaining consent]* so that you can make a careful, voluntary decision about whether or not you want to donate your cells for this research project.

Your signature on this consent form is meant to show that you have had this conversation and that you freely agree to donate your *[insert biological materials]* for this research project.

The information sheet and consent form is not a substitute for actually having this conversation and this detailed information. Please ensure, therefore, that this conversation has provided you with all the information you require.

Please take as much time as you need to ask questions and to talk about this project with your family or friends. You may take this form home with you before you decide what to do. Do not sign this form if you feel pressured in any way by any person to donate your cells for this project. Whether or not you donate *[insert biological materials]* and data for this research project must be your own decision, not someone else’s. In coming to your decision, please take into account in particular the risks (see section 9) and how your data will be used (see section 10), which have been discussed with you.

1. **HOW WILL MY *[INSERT BIOLOGICAL MATERIALS]* BE COLLECTED AND WHAT DATA WILL BE COLLECTED?**

***[As applicable:*** With your approval, *[insert biological materials]* will be taken and data collected from you.

*The precise type (e.g. skin biopsy or blood sample) and quantity of the sample which will be taken (e.g. centimeters and additionally “pinhead-sized” or milliliters and additionally “this corresponds to approximately [...] tablespoons”) should be described using simple, generally comprehensible language. It should also be described when and how the biological materials will be sampled (e.g. one-off extraction during a regular visit to [name of institution]).*

The data to be collected includes personal information, particularly health data *(specify if other data is to be collected, e.g. genetic data).*

*If biological materials are to be sampled and data is to be collected on future visits to [name of institution], this should also be described.****]***

***[As applicable:*** With your approval, your stored *[insert biological materials] (specified)* and related data *(specified)* will be transferred by *[name of institution]* to *[name of institution].****]***

1. **WHAT WILL HAPPEN TO MY *[INSERT BIOLOGICAL MATERIALS]* AND DATA?**

**Your *[insert biological materials]* and data will only be used to create human induced pluripotent stem cells (hiPS cells).** These hiPS cells can grow and divide outside of the body for many years, forming what is called a “stem cell line.” **The stem cell line and related data may be used in future studies by other researchers at *[name of institution]* or other institutions, including in some cases foreign institutions (see section 6).**

***[As applicable:* Genetic analyses will also be performed on your *[insert biological materials]* that might involve sequencing your whole genome.** This may reveal genetic information about you (e.g. a genetic predisposition to specific diseases), which may also affect your family members and your family planning. We explain in more detail what we do to protect your privacy in section 10, “HOW WILL MY PRIVACY BE PROTECTED?”***]***

***[As applicable:* The created stem cell lines will be stored in *[name of biorepository].* This is a place where hiPS cells are kept for future medical research and linked to related data. *(Specify who will have access to the hiPS cells and data for future medical research projects; see also section 10.)]***

There is no guarantee that stem cells will be created from your donated *[insert biological materials]*.

1. **WHAT WILL HAPPEN TO THE CREATED STEM CELLS AND RELATED DATA?**

**It is likely that the stem cells, which would be genetically matched to you, and related data will be stored for many years and made available exclusively for medical research.** Stem cells have the ability to grow and make limitless copies of themselves. **The stem cells and data are likely to be used by researchers at other institutions, including in some cases foreign institutions, and for many other research purposes.**

One possible research objective might involve changing some of their genes in the laboratory (‘in vitro’). Another possible research use might be to study the stem cells by transplanting them into laboratory animals. These are just two common examples of what might happen to the stored stem cells and data in future. It is also possible that the stem cells and data will be used for other future possible research uses that are simply unknown at this time.

**The stem cells and data will not be used for clinical applications. The stem cells and cells derived from them are not intended to be transferred to another person.** However, should, contrary to our original intention, it prove to be the case in future that stem cells or cells derived from them can be used for transplantation, we would contact you again to ask for your consent to use the cells and data for transplantation purposes (see also section 11).

***[As applicable:* It is likely that researchers will perform genetic analysis, including Whole Genome Sequencing (WGS), on the stem cells.** Because the created stem cells will be genetically matched to you, this may reveal genetic information about you (e.g. a genetic predisposition to specific diseases). This information may also affect your family members and your family planning. It is also possible that, after obtaining a court order, genome data could be used in criminal investigations by law enforcement agencies as part of genetic profiling measures. We explain in more detail what we do to protect your privacy in section 10, “HOW WILL MY PRIVACY BE PROTECTED?”***]***

You will **not** be able to decide which institutions or researchers can use the stem cells that were created using your *[insert biological materials]* and data for medical research purposes.

Future uses of stored stem cells and related data must be approved by ethical and scientific review committees to make sure that they are used in scientifically, ethically, and legally appropriate ways. Please contact the individuals listed in section 15 if you have any questions or concerns about the future possible uses of the stem cells and data collected through this research project.

***[Point to consider: Future research involving the creation of gametes and/or embryos –*** *researchers should assess the likelihood that stem cells created from the donated [insert biological materials] may be used in potentially controversial future research. Donors may be uncomfortable with the creation of research embryos or gametes which are genetically matched to them. If the donor’s disease or other factors make this kind of future research a foreseeable possibility, donors should be informed and provided with an opt-out.*

*Example:* Some stem cell researchers study early human development or reproduction. They may want to use stem cells created from your *[insert biological materials]* and related data to create gametes (sperm and egg cells) in the laboratory. These gametes would be genetically matched to you. If gametes are created from stem cells created from your *[insert biological materials]* they will not be used to create embryos or to produce a pregnancy. In giving your consent, you have the right to specifically opt out of permitting your stem cells to be used to create such gametes.***]***

1. **WHAT ARE THE ALTERNATIVES TO DONATING MY *[INSERT BIOLOGICAL MATERIALS]* AND DATA FOR THIS PROJECT?**

One of your alternatives to donating *[insert biological materials]* and data for this project is to refuse to participate at all in this research project.

In addition, you can change your mind at any time without giving a reason and choose not to continue to participate in this research project. This will not have any effect on your current or future medical treatment. You can find more information about this in section 12, “WHAT HAPPENS IF I CHANGE MY MIND?”

1. **WHAT ARE THE POTENTIAL BENEFITS OF DONATING MY *[INSERT BIOLOGICAL MATERIALS]* AND DATA FOR THIS PROJECT?**

**This research project is not designed to give any direct medical benefits to you or anyone else.** You would be donating your *[insert biological materials]* solely to help this research project and research in general.

***[As applicable:*** The stem cells created from your *[insert biological materials]* could be used commercially in the future. By signing this form, you are declaring that you will not receive any direct or indirect financial benefits from any such future commercial use, commercial development, patents or discoveries.***]***

1. **WHAT ARE THE POTENTIAL RISKS OF DONATING MY *[INSERT BIOLOGICAL MATERIALS]*** **AND DATA** **FOR THIS PROJECT?**
2. ***Physical risks***

***[As applicable: Additional material will be taken as part of an already scheduled intervention*** *– precise description of the situation in which the material will be taken (e.g. when taking a regular blood sample), the amount of the additional biological materials which will be taken (e.g. “take an additional 10 ml of blood [corresponding to approximately (…) tablespoons]”) and the physical risk (e.g. “taking this sample does not entail any additional health risk for you”).****]***

***[As applicable: An additional intervention is planned to obtain samples*** – *description of all possible physical risks which could arise when taking the biological materials (e.g. when taking blood: pain at the puncture site; bruising; inflammation of the puncture site or permanent damage to nerves or blood vessels).****]***

***[As applicable: No material will be taken, as only residual material will be used*** *– explanation that only stored biological materials will be used and that donation does not entail any additional health risk.****]***

1. ***Psychological risks***

Some people who donate cells for stem cell research might experience feelings of anxiety or regret. Some may also feel vulnerable and anxious during the consent process.

***[As applicable: As a cell donor for this project you will be asked to undergo medical screen tests for these genetic diseases: (...) (specify). Although this screen test carries no foreseeable physical risks, some donors may feel anxious about their test results.]***

Due care will be taken to help minimize these risks. ***[Specify how this will be done (e.g. follow-up recommended by your physician).]***

1. ***Other risks***

Donating *[insert biological materials]* and data for this project involves some risk to your privacy. Any collection, storage and transfer of data entails the risk of breaches of confidentiality (e.g. the possibility of identifying you), particularly regarding your genetic information. These risks cannot be completely excluded and increase particularly when you yourself make your genetic information available on the internet (e.g. for purposes of genealogy). Genetic data can also be requested by law enforcement agencies. We explain in more detail what we do to protect your privacy in the next section (section 10).

1. **HOW WILL MY PRIVACY BE PROTECTED?**

The records of your involvement with this research project will be kept confidential.

To protect your privacy, immediately after your *[insert biological materials]* have been obtained, any data that directly identify you (name, date of birth, address, etc.) will be replaced by a code (pseudonymized). This code can be used by authorized persons to retrieve your identifying data. ***[If applicable (normally the case):*** Following this, the encoded data set is re-coded again before it is stored.***]*** Your donated *[insert biological materials]* and data will only be used to create stem cells in this form.

All identifying data (name, address, date of birth, etc.) remain at *[name of hospital (physician)]* in which the *[insert biological materials]* and data were obtained. Your identifying data will be stored separately from your donated *[insert biological materials]* and clinical data *(specify if other data, e.g. genetic data, is to be stored)*. After stem cells have been created from your *[insert biological materials],* your identifying data will still remain at *[name of hospital (physician)]* and will be stored separately from your biological materials and clinical data *(add other data, e.g. genetic data, if applicable)*. Identifying the biological materials and data as belonging to you would therefore require the cooperation of *[name of hospital (physician)]* and will only occur in order to obtain additional medical data or to re-contact you where you have agreed to be re-contacted in this way (see section 11). **In no case will personal identifying data be transferred to scientists and/or other unauthorized third parties, such as insurance companies or employers.**

*[It is assumed that all personal identifying data remain at the hospital (physician) in which they were obtained (and are not transferred to the biorepository in which the biological materials are stored). Such a procedure ensures that personal identifying data are protected, in particular by the medical duty of confidentiality. If any other procedure is planned, this must be clearly stated here, and it must be made clear how personal identifying data will be protected.]*

**The encoded stem cells and clinical data *(add other data, e.g. genetic data, if applicable)* may be used in accordance with previously specified criteria in future medical research at institutions (e.g. universities or research companies), including in some cases foreign institutions.** Under certain circumstances these data may be linked to medical data *(add other data, e.g. genetic data, if applicable)* from other databases, provided that all legal and regulatory requirements are met. Stem cells and data that are transferred to institutions may only be used for the defined research purpose and must not be passed on by the recipient for other purposes.

Future uses of stem cells and data for specific research must be approved by ethical and scientific review committees (see also section 6 above).

Although complete privacy protection is difficult to guarantee absolutely, all reasonable measures will be taken to protect your privacy. Reports of research results will always be anonymized, i.e. will not include any information that will identify you. ***[As applicable (for genetic analyses):*** Your whole genome will **not** be published without your express written consent*.****]***

Note: It is possible that, **after** **obtaining a court order, law enforcement agencies may request access to your genome data for genetic profiling purposes during criminal investigations.**

1. **WILL I BE CONTACTED AGAIN?**

In certain cases, it might be useful to contact you again at a later date to ask you for further (follow-up) information and/or for the donation of additional biological materials. We might also want to contact you again to obtain your consent to link your data with medical data *(add other data, e.g. genetic data, if applicable)* from other databases or to obtain your consent to use stem cells created from your donated *[insert biological materials]* or cells derived from them and data for transplantation purposes (see also section 6 above). *[As applicable (for genetic analyses):* We might also contact you again to obtain your consent to publish your entire genome*.]*

***[As applicable:*** Genetic testing on the cells *(specify)* could uncover unexpected information that may be important for your health. There *[is/is not]* a plan in place to share this information with you.***]***

***[Point to consider: The return of health-related incidental findings –*** *if donors are to be informed of any incidental findings, a plan should be implemented. This plan should include what kinds of conditions will be reported, how the results will be validated in a clinical laboratory and how the donor will be informed of the results (e.g. by a clinical geneticist). Donors must be made aware of this policy during the consent process, including what kinds of conditions may be found (e.g. genetic risk factors, infectious diseases, etc.). The right of donors not to be made aware of such information must be respected. Donors must be offered the option of opting out of being informed of any incidental findings. In addition, donors must be told that they can change their mind about being informed of any incidental findings at any time by notifying [name of hospital (physician)]. Donors must also be made aware that they may have to disclose medical information (genome data) received as a result of being informed of incidental findings to other organizations (e.g. before taking out life or health insurance) and could be disadvantaged as a result. It is also possible that, after obtaining a court order, law enforcement agencies may request access to the genome data for genetic profiling purposes during criminal investigations. Donors must also be made aware that information on their genetic material may have implications for their family planning or other family members.*

*Example:* Research on stem cells created from your *[insert biological materials]* may reveal information that could be important to your health (e.g. a genetic predisposition to certain diseases or a suspected serious illness that can be treated or prevented from developing). If this kind of information is found, we would, if you wish us to, contact you again. [Name of hospital (physician)] will, to the extent possible, pass on to you any information that could be important to your health. If you do not wish to be informed of any incidental findings, you can opt out of being contacted by checking the relevant box on the consent form. You can also change your mind about being informed of any incidental findings at any time by notifying [name of hospital (doctor)]. It is possible that you may have to disclose medical information (genome data) received as a result of being informed of incidental findings to other organizations (e.g. before taking out life or health insurance) and could be disadvantaged as a result. It is also possible that, after obtaining a court order, law enforcement agencies may request access to your genome data for genetic profiling purposes during criminal investigations. You should also be aware that information on your genetic material may have implications for family planning and for other family members.***]***

***[Point to consider:*** *It should be made clear who will contact the donor (patient, participant, study doctor, hospital doctor treating the donor, or family physician) from which institution (name of the institution) and whether contact will be made by telephone or in writing.****]***

If you do not wish to be re-contacted, please indicate this by checking the relevant ‘no’ box on the consent form.

1. **WHAT HAPPENS IF I CHANGE MY MIND?**

***a) If you change your mind before stem cells have been created***

**You have the right to withdraw your consent to the use of *[insert biological materials]* and data without giving a reason. This will not have any effect on your current or future medical treatment.**

If you withdraw your consent when you have already donated *[insert biological materials]*, you can decide whether

1. your *[insert biological materials]* will be destroyed by *[name(s) of institution(s)/hospital(s)]* or
2. your *[insert biological materials]* will be used in anonymized form for other scientific research.

***[As applicable:***or c) your *[insert biological materials]* will be returned to *[name of the biorepository].****]***

Anonymizationinvolves deleting the identifying code that can be used to trace a sample back to a specific person. Even after anonymization of your *[insert biological materials],* it is not possible to completely rule out that genetic information may be traced to you via other sources.

You can also decide whether

1. your personal data that has already been collected will be deleted or
2. your personal data that has already been collected will continue to be used in anonymized form.

Once the link between the *[insert biological materials]* and your personal data has been deleted (anonymization), it will no longer be possible to destroy the *[insert biological materials]* or delete the data. In addition, it will no longer be possible to remove data from already completed scientific analyses.

***b) If you change your mind after stem cells have been created***

Once stems cells have been created from your donated *[insert biological materials]*, it is no longer possible to destroy your *[insert biological materials],* unless not all *[insert biological materials]* were required to create the stem cells.

*[Insert biological materials]* which are not used to create stem cells will at your request be destroyed or used in anonymized form for other scientific research. ***[As applicable:***or returned to *[name of the biorepository]*.***]*** However, it will only be possible to carry out your request concerning *[insert biological materials]* that are not used to create stem cells to the extent that it must remain possible to demonstrate that the stem cells that have been created were created from your *[insert biological materials]*.

**You cannot request that the stem cells created from your *[insert biological materials]* be destroyed or should not/no longer be used for medical research purposes.**

Data that is no longer required will be deleted at your request or continue to be used in anonymized form. It will no longer be possible to remove data from already completed scientific analyses.

***c) Person to contact if you change your mind***

If you change your mind and no longer want to participate in this research project, please contact one of the contacts listed on this form without delay (see section 15).

1. **WILL I RECEIVE PAYMENT?**

You will not receive any payment for donating *[insert biological materials]* and data.

***[As applicable:*** You will not be reimbursed for the cost of storing your *[insert biological materials]* in *[name of the biorepository]* for the time period before your *[insert biological materials]* are donated for this research project.***]***

By signing this consent form, you agree that ownership of the *[insert biological materials]* will be transferred to *[name of institution].* In addition, you authorize *[name of institution]* to use your data as described above.

1. **DISCLOSURE OF RESEARCHERS’ POTENTIAL FINANCIAL INTERESTS**

In addition to their scientific interests in this research project, the individuals conducting this stem cell study might profit financially from the research. There may be current or potential financial benefits to the principal investigator, *[name]*, the participating institution(s), *[names]*, and other research institutions or researchers arising from discoveries made through this research project and the stem cells created from your donated *[insert biological materials].* *[Disclose using plain language the researchers’ and the institution(s)’ financial interests in the research.]* If you have any questions or concerns about these matters, please contact the persons listed in section 15.

If you are a *[specify medical condition]* patient, it is important that your treating physician inform you of any personal benefits he or she may gain by your agreement to donate *[insert biological materials]* and data for this research project. *[Disclose here any potential personal benefits the treating physician may receive through this research protocol.]*

The person who has been authorized to provide you with information on your participation and the research project may also have a private interest in this research project. *[Disclose here any potential personal benefits this person may receive through this research project.]*

**Please note that any commercial benefit arising as a result of the research or application will not be shared with you.**

1. **CONTACT INFORMATION**

If you have any questions, please contact:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator

*[Name, address, telephone no., email address]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Administrator

*[Name, address, telephone no., email address]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Review Board

*[Name, address, telephone no., email address]*

**DECLARATION OF CONSENT**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the patient/participant

*[First name and surname, in block capitals]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of birth of the patient/participant

I hereby agree that **my *[insert biological materials]* and data** may be donated **to *[name of institution]*** and can be used to create **human induced pluripotent stem (hiPS) cells** as described in the **information sheet**.

**I agree that stem cells that are genetically matched to me** and data may be used by researchers at other institutions (e.g. universities or research companies), including in some cases foreign institutions, and for **many other research purposes**. **It has been explained to me** that the stem cells and data will **not** be used for **clinical applications** and that the stem cells and cells derived from them will not be transferred to another person.

***[As applicable:***It has also been explained to me that it is possible that the stem cells and data will be used to **create gametes** (sperm and egg cells) for medical research purposes. These gametes would be genetically matched to me. They will not be used to create embryos for research or to produce a pregnancy.

I agree that the stem cells and data may be used to create gametes for medical research purposes. (If you do not agree to this, please check the ‘no’ box below.)

|  |  |
| --- | --- |
| * Creation of gametes for medical research purposes | □ no***]*** |

I transfer ownership of the *[insert biological materials]* to *[name of institution]*.

*[Name of person obtaining consent]* has fully explained to me the nature, importance, scope and risks of participation in this research project in a way that I have understood. I have also read and understood the information sheet and have had the opportunity to ask questions. All my questions have been answered to my satisfaction. I know that my participation in this research project is voluntary, that I can change my mind about participating in this project at any time without giving a reason, and that this will not have any effect on my current or future medical treatment.

I agree that I may be re-contacted at a later date for the following purposes. (If you do not wish to be re-contacted, please check the relevant ‘no’ boxes below.)

|  |  |
| --- | --- |
| * Obtaining further information | □ no |
| * Obtaining further biological materials | □ no |
| * Obtaining my consent to link my data with clinical data *(add other data, e.g. genetic data, if applicable)* from other databases | □ no |
| * Obtaining my consent to use stem cells created from my donated *[insert biological materials]* or cells derived from them and data for transplantation purposes | □ no |
| * *[As applicable:* Feedback on results that are relevant to my health*]* | □ no |
| * *[As applicable (for genetic analyses):* Obtaining my consent to publish my whole genome*]* | □ no |

If I am re-contacted, I will be contacted by ***[name of hospital (physician) in which my biological materials and data were obtained]*** or by the following physician *(please indicate below if required)*:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physician’s name and address

**DATA PRIVACY STATEMENT**

I hereby agree that ***[name of hospital (physician)]*** **collects, stores, and extracts from my medical records** my personal data, in particular health data, as described in the **information sheet**. Together with my **donated *[insert biological materials],*** my data will **– immediately after being obtained**, i.e. before being used to create human induced pluripotent stem (hiPS) cells as intended in this research project – be **pseudonymized (encoded)**.

The **stem cells** created from my **donated *[insert biological materials]****,* which are genetically matched to me, and data may be stored **indefinitely for medical research**.

*[As applicable:* The created stem cell lines will be stored in ***[name of biorepository]***.*]*

The stem cells and data may be used in pseudonymized form for medical research purposes at institutions (e.g. universities or research companies), including in some cases foreign institutions.

*[As applicable:* This could also include transferring the stem cells and data for use in medical research in **countries with less stringent data protection laws**.*]*

**Any report that the researchers publish** will be anonymized,

It has been explained to me that I can change my **mind about participating in this project** at any time without giving a reason, and that this will not have any effect on my current or future medical treatment.

If I notify *[contact point/institution]* that I wish to withdraw my consent **before stem cellshave been created** from my *[insert biological materials],* at my request *[insert biological materials]* that have already been donated and collected data will be destroyed/deleted or anonymized. *[As applicable:* or the donated *[insert biological materials]* will be returned to *[name of the biorepository]*.*]* However, it will no longer be possible to remove data from already completed scientific analyses.

If **stem cells have already been created from my *[insert biological materials],*** **I cannot** request that they be destroyed or not/no longer used for medical research purposes. **Associated data that has already been collected will, at my request, be deleted or anonymized**, as long as they are no longer required in order to use the stems cells for medical research purposes.

I have received a copy of the **information sheet and consent form**. The original remains with *[name of institution]*.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the patient/participant

*[First name and surname, in block capitals]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date

***[Place and date should be entered by the patient/participant.]***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient/participant’s signature

I confirm that I conducted the **patient/participant consultation** and have obtained the **patient’s/participant’s consent**.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the person obtaining consent

*[First name and surname, in block capitals; generally: physician; in some cases, the consultation may also be carried out by qualified biorepository-trained staff, where donation of the biological materials does not require any physical intervention (e.g. if using stored biological materials).]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the person obtaining consent

1. *This sample text is not applicable to the retrieval of somatic cells and data donated as part of a clinical trial of a drug, where these cells and data are (also) to be used other than as set out in the trial protocol. This is because there are legal particulars which need to be observed in this case (e.g. in the data protection statement, if data are to be used in the main study).* [↑](#footnote-ref-2)
2. All red and italicized text must be amended to fit the needs of the individual case. [↑](#footnote-ref-3)