Human Pluripotent Stem Cell Registry

Mandatory Fields

Version 5

2022-04-22

The Human Pluripotent Stem Cell Registry (hPSCreg®) has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement 726320

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1 Steps in cell line data entry

hPSCreg® collects cell line data in two steps: 1) initial registration of a cell line reference code (also known as standard cell line name); 2) Main data collection for all remaining fields in the six tabs of the hPSCreg® data entry interface. To ensure that a minimal baseline dataset is entered before the cell line data record is submitted to hPSCreg® for web publication, hPSCreg® requires a list of mandatory fields be completed.

The following tables, grouped by the tabs in the entry form, indicate which information is mandatory for which cell lines (hESC, hiPSC). Short descriptions are provided for additional clarification.

2 Initial registration of a cell line reference code

2.1 Create a standard cell line name: all cell lines

No.	Field	Mandatory Information	Short description or help text
1	Generator institution	yes	Name of institution that generated the cell line
2	Type	yes	Type of pluripotent stem cell line: hESC or hiPSC.
3	Does a cell line from the same donor exist?	yes	Cell lines from the same donor in hPSCreg® can be linked if there are already existing lines in hPSCreg® from the same donor. If yes, please indicate the relation: • This cell line is a subclone of another stem cell line • Other cell line from the same donor

3 Main data collection

3.1 General Information Tab: all cell lines

No.	Field	Mandatory Information	Short description or help text
1	Cell line name	yes	A systematic name will be automatically be assigned upon initial cell line creation.
2	Generator institution	yes	Name of institution that generated the cell line (collected upon initial cell line creation).
3	Biosamples ID	yes	The ID of the cell line in the EBI Biosamples Database (https://www.ebi.ac.uk/biosamples/). Some IDs might already exist, like for HipSci lines. Click [create] only if there is no associated ID in the Biosamples DB. Subclones should not re-use the ID of the original cell line.
4	Is the cell line readily obtainable for third parties?	yes	If yes, please specify allowance: • research use • clinical use • commercial use

3.2 Donor Information: all cell lines

No.	Field	Mandatory Information	Short description or help text
1	Sex	yes	What is the genetic sex of the donor? Karyotypes containing both X and Y chromosomes are considered male. Karyotypes containing only X chromosomes are considered female.
2	Biosamples Donor ID	yes	The ID of the donor in the EBI Biosamples Database (https://www.ebi.ac.uk/biosamples/). Some IDs might already exist, like for HipSci lines. Click [create] only if there is no associated ID in the Biosamples DB
3a	Is there a disease diagnosed?	yes	Is the donor/embryo associated with any disease / phenotype?

No.	Field	Mandatory Information	Short description or help text
3b	Disease name	yes	If the answer to 3a is “yes”, the disease / phenotype must be given.

3.3 Ethics Tab: hESC lines only

No.	Field	Mandatory Information	Short description or help text
1	Was the embryo established purely for research purposes?	yes	
2	Have both parents consented to the use of the embryo for ESC derivation?	yes	

3.4 Ethics Tab: all cell lines

No.	Field	Mandatory Information	Short description or help text
1	Has informed consent been obtained from the donor of the embryo/tissue from which the pluripotent stem cells have been derived?	yes	The informed consent of a donor of biomaterial provides ethical validation of the provenance of any cell line generated from it, and must be in place before the cell line can be released to the public. If the derivator of the cell line obtained the originating cells or tissue from a commercial vendor, cell bank or other third party, details of the donor consent must be obtained from this third party.
2	Was the consent voluntarily given?	yes	A donation is "voluntarily" given if the donor, custodian or parents have not been subject to duress, coercion or inducement. The decision - to accept or decline donation - will have no effect on the medical treatment or other benefit that s/he will receive.
3	Has the donor been informed that participation will not directly influence their personal treatment?	yes	The donor should be advised that participation in a study or otherwise donating tissue will not affect his or her medical care.

No.	Field	Mandatory Information	Short description or help text
4	Can you provide us with a copy of the Donor Information Sheet provided to the donor?	yes	The document contains the information provided to the donor during the consenting process, before consent is given by the donor. The information usually includes explanations about the purpose of the donation, risks and benefits, what will be done with the samples and data protection issues. Please upload the original consent information sheet, without any personal identifiers. If available, please also upload a copy in English in addition to the original. In the case where the primary cell was obtained from a third party, please obtain the consent information from this third party and upload. Alternatively, please provide contact information of these third parties. It should be noted that the consent information sheet will not be publicly visible. It will only be used by hPSCreg® for cell line validation and certification purposes.
5	Please upload the blank/redacted donor consent form	yes	This refers to the form, which was signed by the donor to document consent (this is not the consent information sheet requested before). Only blank templates or anonymised consent forms must be uploaded here. No personal identifiers of the donor should be deducible. In the case where the primary cell was obtained from a third party, please obtain the consent form from this third party and upload. It should be noted that the consent document will not be publicly visible. It will only be used by hPSCreg® for cell line validation and certification purposes.
6a	Do you (Depositor/Provider) hold a copy of the Donor Consent Form?	yes	If this question is answered “no”, the next question must be answered (6b).
6b	If you do not hold the Donor Consent Form, do you know who does?	yes	If this question (6b) is answered “yes”, contact information for the holder of the Donor Consent Form must be given.

No.	Field	Mandatory Information	Short description or help text
7	Is there other documentation provided to the donor for consenting purposes?	no	This may include cartoons, recordings, assent/dissent information for children or adults, who are unable to provide consent (surrogate decision). If the answer is “yes” a file must be uploaded.
8	Please indicate whether the data associated with the donated material has been pseudonymised or anonymised.	yes	This question relates to the type of data protection applied to the biosample. "Pseudonymised": Identification of the donor is possible as a code was generated whereby the biosample/data can be linked back to the name of the donor. The key to the code can only be accessed by a restricted number of persons as described in the consent documentation. This type of coding is often referred to as "pseudonymised", but also sometimes as "linked-anonymised" or "coded". "Anonymised": Tracing the biosample or derived cells or data back to the donor is not possible when the sample has been anonymised. The sample has been coded, but there is no key linking the biosample/data to the name of the donor, so the material/data are completely anonymised or not traceable.
9a	Does consent explicitly allow the derivation of pluripotent stem cells?	yes	Only one of 9a or 9b should be answered. If both questions are answered, they must not be contradictory.
9b	Does consent expressly prevent the derivation of pluripotent stem cells?	no	Only one of 9a or 9b should be answered. If both questions are answered, they must not be contradictory.
10	Does consent pertain to a specific research project?	no	Has the donor consented to donation of material in the belief that it will be used in only one specific research project or study, and will not be distributed more widely or used for other purposes without further consent?
11	Does consent permit unforeseen future research, without further consent?	no	Has the donor consented to future research to be performed and without requiring new consent?

No.	Field	Mandatory Information	Short description or help text
12	Does consent expressly prevent development of commercial products?	no	Consent to research by a for-profit organisation or any other organisation might not include permission for it to develop a commercial product. This question asks whether the donor has stated a specific objection to the use of the donated material to enable the generation of products that will be sold for financial gain. If so, this restriction on use should be made apparent to any user of a cell line created from the donated tissue.
13	Does consent expressly prevent financial gain from any use of the donated embryo/tissue, including any product made from it?	no	An express prohibition on financial gain from the use or products of donated material needs to be communicated to the user of iPS cells derived from the material.
14	Does consent prevent the DONATED BIOSAMPLE from being made available to researchers anywhere in the world?	no	
15	Does consent prevent CELLS DERIVED FROM THE DONATED BIOSAMPLE from being made available to researchers anywhere in the world?	yes	
16	How may genetic information associated with the cell line be accessed?	yes	There is now evidence to show that genetic data (including mutations, SNPs, STRs, genomics or transcriptomics data) derived from a biosample or cell line could, if used in combination with other publically available information, result in re-identification of the donor. "Open" access means that the donor permits no restrictions on access to genetic information. "Controlled" or "managed" access requires the user to obtain prior authorisation to access genetic data, either by permission of a data access committee or through another management procedure."No information" means that no access policy has been specified by the donor, and that hPSCreg® will therefore treat the data as "controlled access" data. Please note: To enter genetic information associated with a cell line, please go to the tab "Genotyping" and use the relevant fields.

No.	Field	Mandatory Information	Short description or help text
17	Will the donor expect to receive financial benefit, beyond reasonable expenses, in return for donating the biosample?	yes	The answer is "NO" if no financial gain or inducing payment was offered for the donation of the biosample. Reasonable expenses refers to compensation for time and effort involved in donation, including costs incurred (eg travel expenses), as long as these do not constitute undue inducements.
18	Does the consent permit the donor, upon withdrawal of consent, to stop the use of the derived cell line(s) that have already been created from donated samples?	no	
19	Does the consent permit the donor, upon withdrawal of consent, to stop delivery or use of information and data about the donor?	no	
20	Has a favourable opinion been obtained from a research ethics committee, or other ethics review panel, in relation to the Research Protocol including the consent provisions?	yes	If YES: Please provide the name of the ethics panel and approval number.
21	Do you have obligations to third parties in regard to the use of the cell line?	no	In particular: 1. Do any third parties hold intellectual property rights in relation to the use of the cell line? 2. Does the donor consent form expressly identify any restriction on use not already mentioned?
22	Are you aware of any further constraints on the use of the donated embryo/tissue or derived cells?	no	

No.	Field	Mandatory Information	Short description or help text
23	I confirm that I have answered the questions related to ethical provenance and consent information to the best of my knowledge, and that any misrepresentation of the data, intended or otherwise, may result in the revocation of validation and/or certification status of the cell line.	yes	

3.5 Derivation Tab: hESC lines only

No.	Field	Mandatory Information	Short description or help text
1	Date of derivation	yes	On which date has the cell line been generated (the cells isolated from the embryo)? As the handling of hESC lines is restricted for cells before a certain derivation date in some countries, this information might be crucial.
2	Supernumerary embryos from IVF treatment?	yes	Have the embryos been supernumerary from in vitro fertilisation (IVF) treatment?
3	PGD Embryo	yes	Has the cell line been derived from a preimplantation genetic diagnostic embryo?

3.6 Derivation Tab: hiPSC lines only

No.	Field	Mandatory Information	Short description or help text
1	Source cell (line)	yes	Please provide information about the cells that were used for reprogramming. This may include the name of source cell and cell type of the source cell (e.g. fibroblast, peripheral blood mononuclear cell)

No.	Field	Mandatory Information	Short description or help text
2	Vector type for reprogram ming	yes	If a vector has been used for reprogramming, please specify the kind of vector construct used.

3.7 Culture conditions: all cell lines

No.	Field	Mandatory Information	Short description or help text
1	Culture conditions: Medium	yes	Which medium has been used? Please select if a standard, commercially available medium has been used or a self-made one. Please provide details about the composition and/or any supplements.
2	Surface coating	no	
3	Passage method	no	

3.8 Characterisation Tab: all cell lines

No.	Field	Mandatory Information	Short description or help text
1	Analysis of Undifferentiated Cells	yes	For cell line submission, it is recommended to show the expression of at least one surface marker and one transcriptional regulator. By default, if undifferentiated marker expression is not entered into the data input form, the public record will reflect this.
2	Differentiation Potency	yes	For cell line submission, it is recommended to show the differentiation into all three germ layers. This could be for example, by teratoma formation, spontaneous in vitro differentiation, or directed differentiation. By default, if no differentiation potency is entered into the data input form, the public record will reflect this.

No.	Field	Mandatory Information	Short description or help text
3	Microbiology / Virology Screening	no	If the answer is “yes”, screening results for HIV1, HIV2, Hepatitis B, Hepatitis C and mycoplasma can be recorded.

3.9 Genotyping Tab: all cell lines

No.	Field	Mandatory Information	Short description or help text
1	Has the cell line karyotype been analysed?	yes	Has a karyotype been produced for the cell line? If yes, please enter the passage number of the cells karyotyped and the karyotype. You can also upload a karyogram. If the karyotyping has been performed several times, without any changes of the karyotype, please enter only the results of the highest passage tested. If a change occurred in the karyotype of the cells made available to researchers, then that karyotype should be reported. Sublines with different karyotypes should be submitted as different subclones of the original line.
2	STR/Fingerprinting	yes	Have short tandem repeats (STR) or the fingerprint of the cell line been analysed?

3.10 Genetic Modification Tab: only for genetically modified cell lines (subclones)

Here, genetic modifications refer to any modifications to the pluripotent cell lines, other than changes due to reprogramming. Typically, genetic modifications include engineered changes such as gene editing or introduction of a reporter gene construct. If a cell line has genetic modifications compared to its originally derived pluripotent stem cell line, the genetic modification(s) must be described here in at least one of the following cases.

No.	Field	Mandatory Information	Short description or help text
1	Genetic modifications related to a disease or phenotype context	yes	If the cell line is a genetically modified clone, the information on the modification must be provided. This includes: • related disease context • type of modification • chromosomal location (cytoband) of the modification • affected gene
2	Genetic modifications which are not disease related	yes	If the cell line is a genetic modified clone, the information on the modification must be provided. This includes: • type of modification • chromosome location (cytoband) of the modification • affected gene

4 Change History

Version	Valid from	Changes compared to the previous version (short description)
1	October 2017	First version of the quick start cell registration guide for hPSCreg® and EBiSC, including Annex 1. Mandatory Fields

2	See title page	Mandatory fields now provided as a separate document (Annex 2.1.1 Mandatory Fields – this document) to be made available here: https://hpscreg.eu/about/documents-and-governance
		
		This version of the Mandatory Fields shall be released at the same time as the updated Quick Start Guide v1. The Quick Start Guide will refer to the Mandatory Fields document.
		
		• New mandatory fields for EBiSC:
		  ○ surface coating
		  ○ passage method
		  ○ Microbiology / Virology Screening
		• Previous mandatory field is no longer mandatory:
		  ○ Has a favourable opinion been obtained from a research ethics committee, or other ethics review panel, in relation to the PROPOSED PROJECT, involving use of donated embryo/tissue or derived cells?

3	30.09.21	SS: Update document with registered trademark symbol for hPSCreg® 9b not mandatory for hPSCreg®
4	16.11.21	SS: Add question 23 in the ethics section.
5	05.04.22	SS: Remove EBiSC information from the document