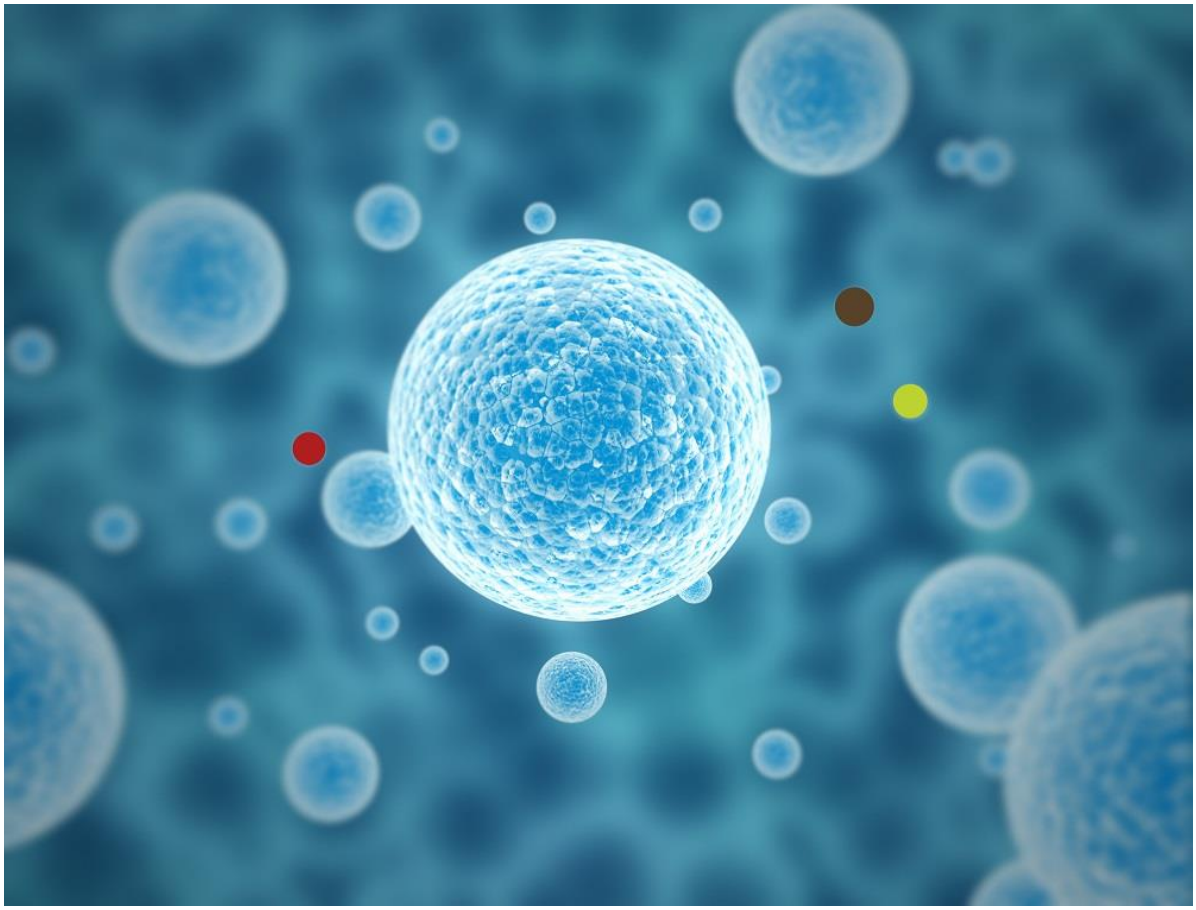
# EBiSC Mandatory Fields for Cell Line Registration

# Version 1

# 2022-03-16



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# 1 Introduction to Mandatory Fields for Cell Line Registration

EBiSC cell line data is captured by registering the cell line as an "EBiSC" line in the human pluripotent stem cell registry (hPSCreg®; hpscreg.eu). A guide to EBiSC cell line data registration can be found on the EBiSC documents website (https://ebisc.org/resources/documents). As hPSCreg® maintains a registry for all human pluripotent cell lines, including both embryonic and induced pluripotent stem cell lines, there are different mandatory field requirements for the general registration (as "hPSCreg®" lines) vs. the specific EBiSC cell line registration.

The mandatory field requirements specify data, which must be given, in order to achieve a basic standard for determining a cell line's ethical provenance and biological properties, for hPSCreg or EBiSC cell line registration.

# 2 Initial registration of a cell line reference code

## 2.1 Create a standard cell line name

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

# 3 Main data collection

## 3.1 General Information Tab

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Cell line name | yes | yes | A systematic name will be automatically be assigned upon initial cell line creation. |
| 2 | Generator institution | yes | yes | Name of institution that generated the cell line (collected upon initial cell line creation). |
| 3 | Biosamples ID | yes | 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 | yes | If yes, please specify allowance:<br>• research use<br>• clinical use<br>• commercial use |

## 3.2 Donor Information

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Sex | yes | 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 | 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 | yes | Is the donor/embryo associated with any disease / phenotype? |

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

## 3.3 Ethics Tab

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Has informed consent been obtained from the donor of the embryo/tissue from which the pluripotent stem cells have been derived? | yes | 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 | 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 | 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 |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 4 | Can you provide us with a copy of the Donor Information Sheet provided to the donor? | yes | 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 | 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 | yes | If this question is answered “no”, the next question must be answered (6b). |

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 6b | If you do not hold the Donor Consent Form, do you know who does? | yes | yes | If this question (6b) is answered “yes”, contact information for the holder of the Donor Consent Form must be given. |
| 7 | Is there other documentation provided to the donor for consenting purposes? | yes | 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 | 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 | yes | Only one of 9a or 9b should be answered. If both questions are answered, they must not be contradictory. |

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 9b | Does consent expressly prevent the derivation of pluripotent stem cells? | yes | yes | 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? | yes | 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? | yes | no | Has the donor consented to future research to be performed and without requiring new consent? |
| 12 | Does consent expressly prevent development of commercial products? | yes | 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? | yes | 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? | yes | no | |

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 15 | Does consent prevent CELLS DERIVED FROM THE DONATED BIOSAMPLE from being made available to researchers anywhere in the world? | yes | yes | |
| 16 | How may genetic information associated with the cell line be accessed? | yes | 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 (EBiSC) 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. |
| 17 | Will the donor expect to receive financial benefit, beyond reasonable expenses, in return for donating the biosample? | yes | 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? | yes | no | |

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 19 | Does the consent permit the donor, upon withdrawal of consent, to stop delivery or use of information and data about the donor? | yes | 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 | 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? | yes | no | In particular:<br>1. Do any third parties hold intellectual property rights in relation to the use of the cell line?<br>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? | yes | no | |

## 3.4 Derivation Tab: hiPSC lines

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Source cell (line) | yes | 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) |
| 2 | Vector type for reprogramming | yes | yes | If a vector has been used for reprogramming, please specify the kind of vector construct used. |

## 3.5 Culture conditions

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Culture conditions: Medium | yes | 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 | yes | no | |
| 3 | Passage method | yes | no | |

## 3.6 Characterisation Tab

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Analysis of Undifferentiated Cells | yes | 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 | no | 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. |
| 3 | Microbiology / Virology Screening | yes | no | If the answer is “yes”, screening results for HIV1, HIV2, Hepatitis B, Hepatitis C and mycoplasma can be recorded. |

## 3.7 Genotyping Tab

| No. | Field | Mandatory Information | | Short description or help text |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Has the cell line karyotype been analysed? | yes | 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 | yes | Have short tandem repeats (STR) or the fingerprint of the cell line been analysed? |

## 3.8 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 |
|---|---|---|---|---|
| | | EBiSC | hPSCreg® | |
| 1 | Genetic modifications related to a disease or phenotype context | yes | yes | If the cell line is a genetically modified clone, the information on the modification must be provided. This includes:<br>• related disease context<br>• type of modification<br>• chromosomal location (cytoband) of the modification<br>• affected gene |
| 2 | Genetic modifications which are not disease related | yes | yes | If the cell line is a genetic modified clone, the information on the modification must be provided. This includes:<br>• type of modification<br>• chromosome location (cytoband) of the modification<br>• affected gene |

## 4. Change History

| Version | Valid from | Changes compared to previous version |
|---|---|---|
| 1 | 16-March-2022 | Mandatory data fields for EBiSC lines has been taken from the hPSCreg document called Annex 2.1.1. Mandatory Fields, Version 1.0, 2021-06-10 |