Procedure for Management of Key Ethics Information and Risks Relating to

Registration of Pluripotent Stem Cell Lines

1. All human PS cell lines proposed for use in hESCreg must be reviewed for appropriate and ethical informed consent.
2. An acceptance form (see below) will be completed and, along with associated documentation (see below) by the PI for the respective data provider/originator of the line. The form will address key ethical issues that could affect use of the cell line for research and human application where appropriate. The ethical provenance of stem cell lines previously approved by a broadly equivalent process will be considered acceptable for the work of hESCreg but documented evidence of the evaluation will still be required.

   The evidence used to demonstrate ethical provenance acceptable for inclusion in hESCreg will include:
   - a copy of the signed consent form (with donor identity blanked out) or a copy of the blank form used for that patient, or a translation of the original in English
   - a description of the consenting process (see risk evaluation form)
   - a statement from a person authorised by the owner or centre where the cell line was derived indicating: 1) a contact and reference for the cell line that in exceptional circumstances would enable the origin and nature of consent to be confirmed and 2) any constraints placed on the use of derived cell lines by the donors of the original tissue.

     Where any of these items are not available the hESCreg PM (project management) group, in consultation with the hESCreg Ethics Advisor and the respective national hESC representative, will make a decision to include or exclude the cell line based on the overall suitability of the evidence provided and the cell line entry will be annotated appropriately to explain the outcome of this analysis.
3. The risk evaluation information will be reviewed by hESCreg and submitted for registration.
4. Should any supplementary evidence or communication arise that would challenge the risk evaluation carried out by hESCreg, a review will be carried out involving the ethics advisor and the respective data provider and a report (including conclusions and any corrective actions) submitted to the coordinator.

Ethics Evaluation Form

Cell line name (s):.....

1) **Risk relating to donor identity**

1.1 If there is an inherited disease associated with the donor is it extremely rare (i.e. only a few families in the country of origin)?

Yes/No/unsure

1.2 If you have responded 'yes' or 'unsure' please attach details of the country of origin and name of the disease if known.

To your knowledge has a genomic DNA profile been made publically available? Yes/No

If you have responded 'Yes' please attach details on the data file and access provisions.

2) **Legal and commercial issues**

2.1 Who is the legal owner/s of the cell line:

.....

2.2 Do you have formal permission from the owner for the line to be distributed to other projects or institutions ?

Yes/No/unsure

2.3 Which method was used to establish the cell line:

....

2.4 For any recombinant DNA vectors used or commercial kits used to generate the cell line, who was the supplier?

.....

2.5 Are you aware of any constraints on the use or distribution of the cell line from the owner or any parties identified in 2.4? Y/N ....

3) **Consenting process**

3.1 To your knowledge was fully informed consent obtained and recorded for the donor tissue used to generate the cell line? Yes/No

3.1.1 Has the donated tissue been anonymised? Yes/No

3.1.2 Has the donated tissue been rendered unidentifiable?

Yes/No

3.1 Have you attached:

a) a copy of the original consent form with donor identity blanked out? Yes/No

b) a blank copy of the consent form? Yes/No

c) an English translation of the consent form? Yes/No

d) a copy of information provided to the donor? Yes/No

e) a statement from a person authorised by the owner or centre where the cell line was derived indicating a contact and reference for the cell line that would facilitate confirmation of the origin and nature of the original consent. Yes/No

3.4 As part of obtaining consent was the donor notified of the following:

3.4.1 That their tissue would be used to create cell lines that can be expanded to provide large quantities of cells for their intended use

Yes/No

3.4.2 That the cell lines may be exploited commercially and that they would not receive any personal financial benefit in relation to the use of the cells

Yes/No

3.4.3 That donation and information derived from their tissue would not directly influence their personal future treatment? Yes/No

3.4.4 That there would be no feedback to them on research or test results?

Yes/No

3.4.5 That the derived cell lines could be used for a wide range of purposes in many labs internationally? Cell lines may be tested for genetic characteristics and microbiological agents?

Yes/No

3.4.6 How their data will be protected? Yes/No

3.4.7 Constraints on use Yes/No

3.4.8 Did the donor request any constraints on the use of the donated tissue or derived cell lines? Yes/No

If yes, list the restrictions: …….

3.6 If the cells are embryonic stem cells, have both parents consented to the use of the embryo for ESC derivation? Yes/No

3.7 Confirm that no incentives were provided for the donation of the tissues or embryos e.g. payment for donated tissues (does not include recovery of donor travel expenses).

Yes/No

Date:

Name/Signature: