



September 6, 2019

Professor MVDr. Aleš Hampl, CSc.
Masaryk University
Žerotínovo nám. 617/9, 601 77 Brno, Czech Republic

Dear Professor MVDr. Aleš Hampl, CSc

I am writing in response to your request for information regarding the consent forms used for the donation of material that resulted in the WA01 (H1) cell line distributed by WiCell.

The ethical provenance of the WA01 (H1) cell line is well established. The complete provenance documentation for the WA01 (H1) cell line was submitted to the US National Institutes of Health (NIH) for review and approval. The donation of the materials used to derive the cell line was determined to be consistent with all existing US laws and regulations, including US Health and Human Services Code of Regulations 45 CFR part 46 subpart A, otherwise known as The Common Rule. Accordingly, the cell line was approved for use in US government sponsored projects. The NIH Registration Number for the cell line is 0043.

Likewise, information regarding the ethical provenance of the cell line, as well as substantial characterization data, was provided to the European Human Pluripotent Stem Cell Registry (hPSCreg) for review and approval. The line has been approved by hPSCreg. Dr. Andreas Kurtz, Director of the hPSCreg, can provide European researchers a certificate indicating this approval, which to our understanding is sufficient to meet EU regulations for working with the cell line.

As part of our confidentiality practices, we do not make consent documents available for viewing, and ask that you rely on the extensive review undertaken by the NIH and the European hPSCreg for assurance of the ethical provenance of the line. Regarding the consent documents used, we can confirm the following:

- Both the donation of the embryo and the derivation of the human embryonic cell line from the donated embryo was conducted using an approved protocol under the oversight of an established Institutional Review Board.
- The cell line was derived from an embryo that was originally created for reproductive purposes as part of assisted reproductive technology procedures, and subsequently not used for that purpose by the donors.
- The embryo was donated for research use once it was determined by the donors that it would not be used for reproductive purposes.
- An informed consent specifically states the use of the embryo will include use in the derivation of human embryonic stem cells for use in research and potential therapies.
- The consent states that there is no advantage to the donors for the donation of the embryo.
- No financial inducements of any kind were offered to the donors at any time.



- The cell line is anonymized, and no information regarding the identity of the donors is ever provided to any researcher.
- The cell line as provided is not genetically modified in any way.

We believe this information should be sufficient to clearly demonstrate that the WA01 (H1) cell line was derived ethically and in accordance with appropriate US regulations. If we can offer any additional assistance or answer any other specific questions, please let us know.

Sincerely,

Tenneille Ludwig, PhD
Director – WiCell Stem Cell Bank