

**Key anticipated regulatory issues for clinical use of human induced pluripotent stem cells.**

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**Public Summary:**

The production of human induced pluripotent stem cells (hiPSCs) has greatly expanded the realm of possible stem cell-based regenerative medicine therapies and has particularly exciting potential for autologous therapies. However, future therapies based on hiPSCs will first have to address not only similar regulatory issues as those facing human embryonic stem cells with the US FDA and international regulatory agencies, but also hiPSCs have raised unique concerns as well. While the first possible clinical use of hiPSCs remains down the road, as a field it would be wise for us to anticipate potential roadblocks and begin formulating solutions. In this article, I discuss the potential regulatory issues facing hiPSCs and propose some potential changes in the direction of the field in response.

**Scientific Abstract:**

The production of human induced pluripotent stem cells (hiPSCs) has greatly expanded the realm of possible stem cell-based regenerative medicine therapies and has particularly exciting potential for autologous therapies. However, future therapies based on hiPSCs will first have to address not only similar regulatory issues as those facing human embryonic stem cells with the US FDA and international regulatory agencies, but also hiPSCs have raised unique concerns as well. While the first possible clinical use of hiPSCs remains down the road, as a field it would be wise for us to anticipate potential roadblocks and begin formulating solutions. In this article, I discuss the potential regulatory issues facing hiPSCs and propose some potential changes in the direction of the field in response. Original submitted 20 April 2012; Revised submitted 25 May 2012; Published online 26 July 2012.

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