

Stem cells on South African shores: Proposed guidelines for comprehensive informed consent

To the Editor: In October 2012, Shinya Yamanaka and Sir John Gurdon were awarded the Nobel Prize in Physiology or Medicine for their pioneering research into the reprogramming of mature cells into a pluripotent state. The technology developed by Yamanaka and colleagues allows researchers to turn terminally differentiated somatic cells back into a stem-cell state.¹ These induced pluripotent stem cells (iPSCs) can be cultured indefinitely in the laboratory, and can undergo directed differentiation into any cell type of interest. This is highly beneficial for disease-modelling studies, since researchers are able to culture cells that are not normally obtainable, such as neurons or retinal cells. Furthermore, the differentiated cells can be used to test potential therapies in patient-derived cells, and may even be used for future therapeutic cell transplantation.

iPSC research is no longer a 'foreign' technology, with laboratories from at least two South African institutions employing these methods for 'disease-in-a-dish' modelling. Given the seemingly endless possibilities for future iPSC-based research, we wish to highlight the challenges associated with obtaining comprehensive informed consent from research participants. A recent review from the National Institutes of Health in the USA outlined the standards, policies, protocols and regulations required for cell-based therapies, and addressed specimen collection for iPSC research.² The authors pointed out that providing accurate information about what will not be done with a research participant's specimen is almost impossible, given the rapid advances in research. We propose that the informed consent documentation must be explicit when addressing these matters. In South Africa, for example, definitive assurance could be given that germline cell derivatives and reproductive applications will not be attempted or developed with the generated iPSCs, as current legislation prohibits certain uses of biological samples, such as the reproductive cloning of humans (National Health Act 61/2003: 57(1)). These assurances will need to be reviewed regularly, however, so that research possibilities are not stultified by bureaucracy and avoidance of debate.

In many respects, iPSC research seems to provide more questions than answers and this creates a new challenge for researchers and research ethics committees.³ A balance must be found between consent that is too broad and indistinct, or too narrow, which may hinder future research prospects. Some commentators favour a 'tiered' approach to consent, which allows participants to consent to specific uses, and to stipulate their wishes regarding banking and sharing their biological material with other researchers, and whether they wish to be re-contacted in the event that further use of their samples is needed. This would enable individuals to opt out of sensitive areas such as gamete formation, reproductive research, commercialisation and genetic manipulation.

In the South African context, we need to determine efficacy and safety by using iPSCs as pre-clinical cellular models, in preparation for future therapeutic development and human clinical trials. By addressing the scientific, legal and ethical implications of establishing and using iPSCs in the laboratory, we can use this time constructively and productively to develop prospective policies for the use of iPSCs in future therapeutic applications.⁴

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