

## **1 Ethics Policy**

### **1.1 INTRODUCTION**

The pharmaceutical industry's objective is to develop new medicines that deliver patient benefit, especially in areas of unmet medical need. Drug discovery and development is a lengthy process, with many candidate medicines failing to make it through the process because of lack of efficacy and unexpected safety issues.

Advances in science and technology are occurring at an ever accelerating rate and companies are interested in how new technologies can be applied to improve drug discovery, reducing the likelihood of candidate medicines failing in late development. While this collaboration of companies is not interested in developing stem cell technologies for direct therapeutic use, they do offer an opportunity to support discovery of new medicines. If successful, the outcomes will not just be long-term benefit for patients in terms of new medicines, but also a reduction in the number of candidate medicines failing in clinical research, further enhancing safety for volunteers and potentially reducing the number of animals used.

The Stem Cells for Safer Medicines collaboration is therefore interested in the potential of differentiating human stem cells (embryonic, cord-blood derived and adult) into normal human cells, such as those in the liver (hepatocytes) and heart muscle (cardiomyocytes). If this is possible in a reproducible and consistent way, these cells could be used to evaluate the effect a potential new medicine has on the normal cell, and to provide a more accurate prediction of drug metabolism and toxicity outcomes in man. We believe this would represent a significant step forward in increasing the human relevance of studies at an earlier stage of development of a potential new medicine and would help us to overcome the current limitations that a restricted supply of normal cells presents.

Research utilising embryonic stem cells is, understandably, an area of science that raises concerns, and all steps should be taken to ensure a sound ethical framework. The UK has for many years adopted a clear regulatory and ethical framework, arguably leading the world by the regulation of such research by the Human Fertilisation and Embryology Authority and the UK Stem Cell Bank Steering Committee.

Nevertheless, while the Stem Cells for Safer Medicines collaboration is a UK-based initiative, its members are based across the globe. Consequently it is essential that any research undertaken takes a global, not just UK, perspective and ethical approach, and it evolves to reflect new developments in technologies and science in this rapidly moving area.

### **1.2 OBJECTIVES**

This Ethics Policy has been developed to support the vision and objectives of the collaboration's overall initiative, namely:

- *To enable the creation of a bank of stem cells with open protocols and standardised systems in stem cell technology that will enable consistent differentiation of stem cells into stable homogenous populations of particular*

*cell types, with physiologically relevant phenotypes suitable for toxicology testing in high throughput platforms.*

As pharmaceutical companies operate in a global environment, any research carried out by Stem Cells for Safer Medicines will reflect relevant local, national and international ethics policies and legislation and be monitored by an independent Ethical Review Board.

### 1.3 GUIDING PRINCIPLES

Research sponsored by or co-ordinated through the Stem Cells for Safer Medicines collaboration will only utilise stem cell lines that are fully compliant with the following criteria and reflect the conditions for inclusion in the NIH Registry<sup>1</sup> in the USA and the UK Stem Cell Bank<sup>2</sup>.

- The stem cells must have been derived from adult, cord-blood sources or unused fertilised eggs created for reproductive purposes (embryonic stem cells).
- Fully informed consent must have been obtained prior to the donation of a fertilised egg or other source of stem cell lines for scientific research.
- There must be no financial or other inducements for donation of a fertilised egg, cord-blood or source of adult stem cells.
- Donation, management and distribution must comply with guidance and ethical codes in the countries from which the stem cell lines were sourced.
- Only stem cells lines already banked or registered to be banked should be used.
- Prior to any research utilising cell lines derived from human embryonic stem cells, there must be a clearly defined purpose to increase knowledge about serious disease and/or to apply such knowledge in developing treatments for serious disease.
- Stem Cells for Safer Medicines and research funded by the collaboration will not use human-animal hybrid cloned stem cell lines or cytoplasmic hybrids (“cybrids”).

### 1.4 ETHICAL ADVISORY BOARD AND FUTURE REVIEW

Science progresses rapidly and new sources of stem cells – for example, adult or cord blood derived – are arising all the time. Currently, adult stem cells can only create a narrow range of cell lines dependent upon their origin (that is, they are multipotent, as opposed to human embryonic stem cells, which are pluripotent). Stem cells derived from cord blood are likely to be pluripotent, yet the successful derivation of these in sufficient numbers remains unproven. This may not always be the case. Use of other lines will be reviewed as the ethical, legal and scientific environment develops and will be referred to an independent SC4SM Ethical Review Board – any changes to this policy requires the unanimous support of the SC4SM membership.

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<sup>1</sup> <http://stemcells.nih.gov/research/registry/>

<sup>2</sup> <http://www.ukstemcellbank.org.uk/>

## Stem Cells for Safer Medicines: Ethics Policy

The independent Ethical Review Board (ERB) will be established in the first half of 2008 and provide advice on the ethical, social and legal framework for stem cells research. The ERB will review this policy in the phase 1 of the programme and advise the company in light of the Five-year Scientific Strategy that will be published in the middle of 2008, taking into consideration scientific developments covering all forms of stem cells lines (adult, cord-blood derived and embryonic) and public debate and opinion in a global context.

The Chairman of the Ethical Review Board will provide advice to the Stem Cells for Safer Medicines Board and Members' Council and report on the findings of the Ethical Review Board.

The Ethical Review Board will continue to review this policy and make any recommendation for amendments in light of scientific or other developments to the Council.

### **1.5 IMPLEMENTATION AND AUDIT**

Any proposal to engage in research using human adult, cord-blood derived or embryonic stem cells or cells derived from them on behalf of or in partnership with Stem Cells for Safer Medicines must fall within this policy and all relevant standards for human stem cell research and banking, and use of human tissues. All research will be subject to peer review both for scientific content and, if necessary, ethical review.

All research contracts and conditions of grant awards will require those funded by the collaboration to comply with this Ethical Policy. All researchers will be required to have auditable procedures that can ensure only cell lines allowed by this policy are utilised in such research. An independent auditor will be appointed to review compliance during the research programme.