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GOVERNANCE OF STEM CELL SCIENCE: MULTIPLE MODELS & SIMILAR OUTCOMES

Geoffrey Lomax*

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^{*} Senior Officer to the Standards Working Group, California Institute for Regenerative Medicine.

Governments and non-governmental organisations have been active in developing policies to govern stem cell research. Various international policy frameworks, specifically designed to address human stem cell research policy, are described in the literature and were discussed at this workshop.¹ As Rosario Isasi suggests, during the workshop and in previous publications, there is a trend towards policy convergence surrounding fundamental ethical issues (e.g. respect for autonomy and confidentiality; respect for the human body by restricting the use of monetary payments and financial incentives for donation; ethics review and oversight, etc.).² This policy-level convergence appears to have emerged despite very different approaches to the governance of stem cell science.

Workshop speakers described a range of approaches to stem cell governance and oversight. For example, the UK and certain American states have developed liberal frameworks characterised by a high degree of plurality in policy development and implementation. The research program of California was initiated after a voter referendum. In New York and the UK, spirited public debate gave rise to research programs through legislative action. Subsequently, in some American states, the UK and elsewhere, there has been direct public involvement in policy development through participation in governance committees, ethics councils and consultation efforts.

The Seventh European Union Framework Programme (FP7) for research and development includes ethical criteria for funded research. While the criteria with regard to use of human embryos are restrictive - comparable to those applied by the US National Institutes of Health Guidelines for Human Embryonic Stem Cell Research - the FP7 Framework reflects positions of consensus regarding autonomy, confidentiality and financial payments.

The workshop included representatives from countries in which policy controversies surrounding the human embryo are greatly attenuated, namely Iran, China and India. Policies in these jurisdictions echoed consensus positions regarding research ethics. The International Society for Stem Cell Research Guidelines for the Conduct of Human Embryonic Stem Cell Research was cited as a formative policy document.

Collectively, workshop speakers reinforced the theme of policy level convergence for embryo research among jurisdictions seeking to advance stem cell science. Participants suggested this convergence represented the natural extension of human research ethics policy to embryonic research. However, they also suggested that the trend towards uniform standards is driven in part by (1) the need to forge international collaborations and (2) the desire to publish findings in high-impact journals.

The suggestion that requirements for collaboration and publication are a driver for policy development serves as an interesting discussion point. To some extent, the supposition that research norms drive policy stands in contrast to the calls for public governance of science that have become increasingly popular over the past decade.³

¹ O Corrigan et al, Ethical, Legal and Social Issues in Stem Cell Research and Therapy: A Briefing Paper from Cambridge Genetics Knowledge Park (2005).

² RM Isasi, "Policy Interoperability in Stem Cell Research: Demystifying Harmonization" (2009) 5 *Stem Cell Rev*iew 108-15.

³ H Longstaff and M Burgess, "Recruiting for representation in public deliberation on the ethics of biobanks" (2010) 19 *Public Understanding of Science* 212-224.

Although, it should be recognized that normative science and public governance are not necessarily mutually exclusive, the harmonisation of ethics policy issues appears to have occurred independent of the level of public governance / participation. This observation resulted in a series of discussion questions that might be considered in future policy research:

- To what extent are plurality and public participation important to research policy development?
- What are measures of effectiveness for successful public participation?
- To what extent are non-regulatory bodies (journals, professional societies) effective arbitrators of ethics policy?
- Does international consensus in ethics policy have a positive impact on research implementation?

Workshop participants also suggest that jurisdictional variance exists in the implementation of ethics policies. In other words, while policy statements are an important step towards the ethical conduct of research, culture and ethical norms may result in operational differences. Based on field observations and survey data, participants suggest equivalent policies may not correspond to identical implementation processes. However, there was a general sense the international policy consensus serves to create a trajectory toward enhanced ethical conduct of research.