

Regulating expression: the governance of human developmental genetics research.

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The Background

The DGEMap project aims to design a pan-European infrastructure that will unite a currently fragmented research effort. A core component of the project is an exploration of the ethical, social and legal aspects of this area of research, given the scientist's need to use human embryonic and foetal tissue.

We have conducted a review of the literature and begun to explore the diverse legal regimes throughout the EU. Our considerations of the ethical and social aspects of DGEMap research are informed by studies of tissue banks and other research on ethically contentious tissues and entities.

The Survey

- 59 responses representing 24 nationalities.
- Average respondent has worked in genetics for 21 years.
- 21 described themselves as religious.
- Only 3 respondents thought EU legislation on working with embryos was too liberal.
- 23 said local regulation restricted their research.
 - Most thought restrictions were reasonable and justified.
- Only 6 respondents would relocate to more liberal regime to continue work.
- 25 thought regulation of research using human embryos was unclear or ambiguous.
 - However only 2 respondents thought ambiguity helped their research.
- 42 thought ethical oversight adequate, only 8 of whom thought it was restrictive.
- 28 respondents said there was no ethics training for any staff and 12 did not know.
 - Of these, 33 thought ethics training should be made available to staff at all career stages.

The Challenges for Governance

The major challenges identified for the governance of the DGEMap infrastructure include:

- Stewardship
 - Control and limitations on use.
 - Provenance of tissue.
 - Consent: general or informed?
- Anonymisation
 - Anonymous or link-anonymised?
 - Implications for feedback and storage of genetic information.
- Disposal of tissue
- Public engagement
 - Reactive or Proactive?

The Ethical Issues

The ethical issues DGEMap raises result from the contentious nature of the source of the human tissue required. Technical and, especially, legal constraints on the growth of human embryos *in vitro* mean that relevant tissue must be sourced from women undergoing termination of pregnancy.

The collection and use of such tissue has been governed, since 1989 in the UK, by the Polkinghorne guidelines. However, changes in attitudes to consent for donating tissue to medical research and the recent establishment of the Human Tissue Authority has led to questioning of Polkinghorne's continuing suitability.

There are also arguments to be explored regarding the justification for the use of such tissue. Human developmental geneticists have noted disparities between the results of gene expression between human and model organisms. The rates of maldevelopment in pregnancies and links to late onset disease are also common justifications for research.



The Symposium

Twenty two delegates specialising in developmental genetics, law, sociology, philosophy and ethics gathered in Newcastle in February 2007 with the aim of helping us develop a framework of considerations for a governance framework for the DGEMap infrastructure.

The themes that emerged in discussions were:

- Complex, contradictory and constantly shifting law.
- Outdated professional guidelines, perhaps inadequate for pan-European application.
- Difficulties of informed consent in relation to tissue banks and compliance with Polkinghorne.
- The merits of anonymous tissue collections.
- Inconsistencies in terminology, "embryo" now almost synonymous with entity created in IVF.
- Public engagement and debate is important and opportunities should be carefully chosen and taken.



Conclusions

The DGEMap project offers the opportunity to develop an ethically robust research governance framework, for scientists working with early human developmental tissue, that is aspirational rather than merely pragmatic. Scientists have revealed a desire to lead a public dialogue and to engage with ethicists to train staff at all stages of their careers.

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