

EMPIRICAL ETHICS

Consent to the use of aborted fetuses in stem cell research and therapies

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Abstract

This paper identifies the legal and policy framework relating to the use of aborted fetuses in stem cell research and therapies and contrasts this with the collection of embryos for research. It suggests that more attention should be given to questions about the kind of consent sought by researchers from women and that there should be more transparency about how aborted fetuses are used. It reports on variability in current practices of research ethics committees and researchers and uncertainty about the guidance available to them. It argues that there is a need for wide public discussion about the policy issues relating to fetal tissue use in stem cell research and the need for clarification of the law in this area.

Aborted fetuses are widely used in medical research, both in established fields such as developmental biology and virology, and more recently in pushing back the frontiers of stem cell science. Aborted fetuses are 'produced' by a legal but nonetheless controversial procedure, and their association with pregnancy and reproduction makes their status as human tissue ambiguous. Yet the issues they provoke have received little public scrutiny. This paper addresses two of them: first, what kind of consent should be sought by medical researchers from women undergoing a termination; and second, how transparent should the collection of aborted fetuses be? We draw on some preliminary findings of research into the social, ethical and political conditions under which aborted fetuses are collected and used in stem cell research.¹

English law does not recognize a distinction between a fetus *in utero* and the woman in which it is implanted; put another way, tissue of the fetus *in utero* and that of a fetus *ex utero* (up to 24 weeks gestation and that has not

been born alive) is the woman's tissue and can be treated like other 'residual tissue' following clinical and diagnostic procedures, of which many millions are carried out each year.² As such, aborted fetuses fall under the provisions of the Human Tissue Act 2004.³ The separate provisions of the Human Fertilisation and Embryology Act 1990⁴ afford the embryo created *in vitro* a high level of protection, and the Human Fertilisation and Embryology Authority (HFEA) regulates the creation and use of embryos in treatment and research, including stem cell research. Embryos are regarded in law as exceptional. Together with the EU Tissue and Cells Directive 2004,⁵ this forms a new legal framework for the collection of *all* human tissue for research and therapeutic use.

Policy makers, however, acknowledge that the public regard pregnancy-related tissue differently to other residual tissue. The distinctive status of the aborted fetus is recognized in the Polkinghorne Guidelines (1989), which currently govern fetal research. The Polkinghorne Guidelines are named after Reverend Dr John Polkinghorne, chairman of the committee which drew them up. The committee took the view that only tissue from the dead fetus *ex utero* is ethically available for use; the 'supply' of fetal tissue must be separated from the practice of research and therapy – in other words, the investigator must not be involved in the procedure (the 'separation principle'); the method of terminating the pregnancy must not be influenced by research requirements; and consent for research should be general, not specific (that is, details of the research which might use the material should not be specified to the woman). The committee had been persuaded that women might be influenced in their decision to have an abortion by the possibility of the fetus being used in a particular way; for example, they might conceive a pregnancy deliberately to provide neural tissue for transplantation into a relative with Parkinson's disease.

In the years since the Polkinghorne Guidelines were drawn up, specific and not general consent to the use of

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human tissue in research has become the norm, yet – controversially – because of the way consent guidelines have been framed with regard to women undergoing termination of pregnancy, they have been treated differently.

The working party convened in 2000 by the Medical Research Council (MRC) to produce guidelines on the collection of human tissue and biological samples for use in research insisted that specific consent is sought for the use of all human biological material in research, but made an exception of aborted fetuses, where general consent must apply.⁶ Three years later, responses to *Human Bodies, Human Choices*, the consultation document which informed the Human Tissue Act, revealed some agreement on a move towards specific consent in relation to the collection of aborted fetuses but also some resistance to providing women with a great deal of information about any future research.⁷

The Human Tissue Authority (HTA), the competent authority with responsibility for both implementing the EU Tissue and Cells Directive and the Human Tissue Act, has issued guidance on the general requirements and good practice regarding the need for consent in relation to the storage and use of human tissue. Section 66 of its Code of Practice on consent states:

‘The law does not distinguish between fetal tissue and other tissue from the living – fetal tissue is regarded as the mother’s tissue. However, because of the sensitivity attached to this subject, consent should be obtained for the examination of fetal tissue and for its use for all scheduled purposes, regardless of gestational age. It is considered good practice that, wherever practicable, consent should also be obtained for the use in research of non-fetal products of conception. Research Ethics Committee approval is always required for the use of fetal tissue and products of conception in research.’⁸

However, the Human Tissue Act does not define what constitutes appropriate consent and the HTA has not yet provided any guidance save for a reminder that common law applies.

We found a wide variability in the kinds of information being given to women being asked to agree to the use of aborted fetuses in stem cell research. Some information sheets describe at length the project for which aborted fetuses are sought; some provide a brief account of several different projects in which the fetus might be used; some set out briefly a very broad field. None offer women a choice to agree to the fetus being used in some projects but not others. Yet some projects are funded by the MRC, whose model consent form for research involving new samples of human biological material allows people to agree to or refuse the use of their tissue in possible future research projects, genetic tests of known clinical and/or predictive value, and other genetic research.

This variability suggests uncertainty on the part of members of Research Ethics Committees about whether or not general or specific consent is required or desirable. No-one has taken responsibility for clarifying the situation. Yet, following a complaint by Professor Austin Smith (a leading stem cell scientist) to members of the House of Commons’ Science and Technology Committee about the failure of the HFEA to provide guidelines for drawing up consent forms for embryo donors,⁹ the MRC agreed to sponsor a review of the paperwork by a nationwide net-

work of stem cell co-ordinators working in IVF clinics associated with stem cell laboratories, a review expected to result in a standardized approach organized around the specific consent requirements of the Human Fertilisation and Embryology Act.¹⁰ While it may be considered unnecessary or inappropriate to prescribe a uniform approach in relation to information about the use of aborted fetuses in research, there is clearly a need for agreement in this area.

The Polkinghorne Guidelines were drawn up by a committee of four people convened to consider concerns about the use of neural tissue of aborted fetuses in experimental transplants into the brains of people with Parkinson’s disease.¹¹ Whether or not the Guidelines meet the requirements of stem cell scientists is unclear. Nor is it possible to tell whether some operate within them while others do not, and whether those deviating from them do so with or without the agreement of the Research Ethics Committee which reviewed their proposal: the Polkinghorne committee did not see the need for a system of public oversight. Yet in the year following publication of its Guidelines, the Human Fertilisation and Embryology Act created the HFEA, which is charged with (amongst other things) oversight and inspection of how embryos created *in vitro* are sought and used in research.

The government has responded to requests for the amendment of the Human Fertilisation and Embryology Act to accommodate the requirements of stem cell scientists.¹² The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 extended the list of purposes for which human embryo research could be licensed by the HFEA to include research aimed at understanding the development of embryos, or understanding or treating serious disease; that is, it effectively provides a regulated space in which human embryos might legitimately be used in stem cell research.¹³ The Department of Health is responsible for keeping the Polkinghorne Guidelines up to date. Its first and only official amendment was issued in 1995 in an NHS circular which encouraged investigators to source frozen fetal material from the MRC Fetal Tissue Bank at Hammersmith Hospital (now closed), which then stood as an intermediary body between source (a woman) and user (a researcher).¹⁴ However, the Department also recognized that some research needs ‘fresh’ material and allowed investigators to establish what it called ‘local arrangements’ – that is, to find a compliant local hospital or clinic.

The Department of Health’s modification of the Polkinghorne Guidelines took place without public debate. Yet nowadays, in situations such as abortion where moral pluralism is found, the importance of transparency in policy making is emphasized. The HFEA boasts of its capacity to maintain public confidence in a controversial field and takes the lead in encouraging awareness and debate about research and treatment involving human embryos. As Suzi Leather, HFEA’s current chair, told the House of Commons Science and Technology Committee, they do this by ‘communicating what we are doing, communicating what the possibilities of science are, what the benefits and disbenefits are.’¹⁵ In contrast, Research Ethics Committees, who are responsible for interpreting and implementing the Polkinghorne Guidelines, have no remit in relation to public engagement. Indeed, whereas the

HFEA meets in public, they deliberate behind closed doors.¹⁶ There is currently no publicly available information about the projects using fetal tissue in research, whereas the HFEA, in its annual report, lists all the research projects which it has approved.

In our view what is needed is a wide public discussion about the issues surrounding the use of fetal material for stem cell and other research.¹⁷ A system of governance which provides clear oversight and transparency will also provide protection for researchers using fetal material. Moreover, if the UK environment is to continue to be seen as facilitating stem cell research because of its strong approach to regulation, the current contradictions between the guidance set out in the Polkinghorne Guidelines and the law need clarification.

References

- 1 The research falls under a programme of research looking at social, ethical and political aspects of stem cell science sponsored by the Economic and Social Research Council. RES -340-25-0002
- 2 Human Tissue Authority. *Code of Practice 5: Removal, Storage and Disposal of Human Organs and Tissue*. Available at http://www.hta.gov.uk/_db/_documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_5_-_Removal.pdf (accessed July 2006)
- 3 *Human Tissue Act 2004*. London, TSO
- 4 *Human Fertilisation and Embryology Act 1990* (c 37). London: HMSO
- 5 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on *Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells*. Official Journal L102 48-58
- 6 Medical Research Council. *Human Tissue and Biological Samples for use in Research: Operational and Ethical Guidelines*. London: MRC, 2001
- 7 Department of Health. *Human Bodies, Human Choices: Summary of Responses to the Consultation Document*. London: DoH, 2003
- 8 Human Tissue Authority. *Code of Practice 1: Consent*. Available at http://www.hta.gov.uk/_db/_documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_1_-_Consent.pdf (accessed July 2006)
- 9 Memorandum submitted by Professor Austin Smith, Centre for Genome Research, University of Edinburgh, to The Science and Technology Committee. *Developments in Human Genetics and Embryology*, Appendix 4. London: HMSO, 2002. Available at <http://www.publications.parliament.uk/pa/cm200102/cmselect/cmsctech/791/791ap06.htm> (accessed 14 July 2006)
- 10 Franklin S. Embryonic Economies: The double reproductive value of stem cells. *Biosocieties* 2006;1:71-90
- 11 *Review of the Guidance on the Research Use of Fetuses and Fetal Material*. Cm762. London: HMSO, 1989
- 12 *Human Fertilisation and Embryology (Research Purposes) Regulations 2001*. London: TSO, 2001
- 13 *Human Fertilisation and Embryology (Research Purposes) Regulations 2001*. Statutory Instrument 2001 no.188. Available at www.opsi.gov.uk/si/si2001/20010188.htm (accessed 21/11/2005)
- 14 Department of Health. *Guidance on the Use of Fetal Tissue for Research, Diagnosis and Therapy*. London: DoH, 1995
- 15 Leather S. Minutes of evidence. In: The Science and Technology Committee. *Developments in Human Genetics and Embryology*. London: HMSO, 2002. Available at <http://www.publications.parliament.uk/pa/cm200102/cmselect/cmsctech/791/2042403.htm> (accessed 14/07/2006)
- 16 Ashcroft R, Pfeffer N. Ethics behind closed doors: do research ethics committees need secrecy? *BMJ* 2001;322:1294-6
- 17 Kent J, Pfeffer N. Regulating the collection and use of fetal stem cells. *BMJ* 2006;332:866-7