VIEW POINT
Journal of Cellular Biochemistry 108:1–2 (2009)
Journal of Cellular Biochemistry

Surgeons and Scientists: Working Together in Embryo Research

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ABSTRACT

Most surgeons in academic hospitals will have had a request from an enthusiastic research scientist to take samples of tissue during an operation. It seems reasonable and most patients will respond positively. But of course it is not quite that simple. The regulation of donation of human tissue for basic research is clearly defined but usually less rigorous than that which covers translational research and clinical trials. An exception has been the donation of embryos for embryonic stem cell derivation. The specific issues related to obtaining cells from patients for this work has resulted in a different relationship between scientist and clinician. This will be considered. J. Cell. Biochem. 108: 1–2, 2009.

KEY WORDS: EMBRYO RESEARCH, EMBRYO DONATION, MEDICAL ETHICS, EMBRYONIC STEM CELLS

Clinical trials are governed by internationally accepted codes of practice (Declaration of Helsinki, World Medical Association). Claims that are made without appropriate proof of good practice are rightly challenged. The relationship between the scientist and the clinician in early clinical studies is well defined with strict regulatory oversight, particularly if a potential therapeutic product is being developed. Under these circumstances there tends to be a clear separation between the rewards for the scientist (IP rights and royalties) and the benefits to the clinicians (therapeutic success and enhanced clinical practice) although both will benefit from the sense of achievement.

Legislation and regulation of the procurement of human tissue for basic research follows similar ethical principals but in practice varies considerably throughout in the world. Scientists continue to move between countries as necessary to follow their interests but the fundamental principal underpinning human research, that it must be based on informed consent given without coercion, is paramount. Regardless of the quality of the science, results of research undertaken without such consent will be discredited.

Most patients who give a blood sample for a laboratory test would have no concern about any serum remaining after the analysis being used for further laboratory research. In practice in the UK, most patients are surprised that their consent is even requested. Similarly, tissue taken at routine operations is discarded as clinical waste after examination. It could be argued that to use this tissue for ethically approved study is preferred and, in the interests of solidarity, presumed consent is appropriate. Ethical opinion on this remains divided.

The nature of the tissue that is to be used for research impacts on the regulation of the donation process. Few would argue that urine has any special status. The distaste engendered by this material relates to its collection and handling rather than to any intrinsic status. This is despite the fact that this material holds information about the unique genetic identity, wellbeing and personal habits of the individual. A kidney taken from a living donor for transplant has immense importance as a potential life-giving organ to a recipient with renal failure. A diseased kidney removed because it caused complications has no intrinsic value and is discarded as waste. A cadaver kidney has no value if it goes to the crematorium despite being a potential organ for transplant. It is the purpose for which that tissue may be used that gives it its practical value and ethical status.

In relation to gametes and embryos, the issue has a higher profile despite similarities in the underlying ethical principals. Most sperm are disposed of as human waste. Despite the potential to make a child, this is never achieved unless coitus occurs at the right time in a fertile woman, and even then the odds of an individual sperm making a baby are less than 1 in millions. Although there are fewer eggs produced, of the thousands that a woman is born with, only an average of 2 per woman is likely to make a baby. Thus each individual gamete has little intrinsic value.

The potential of the gamete changes following fertilization. It becomes closer to that of the kidney in the cadaver—with absolutely

Grant sponsor: Wellcome Trust; Grant numbers: GR070705AIA 2003, MRC GO300486 2004, MRC GO301182 2005, MRC G0601157 2007.
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Received 2 June 2009; Accepted 2 June 2009 • DOI 10.1002/jcb.22261 • © 2009 Wiley-Liss, Inc.
Published online 6 July 2009 in Wiley InterScience (www.interscience.wiley.com).

no value unless it implants in the uterus but with the potential to create a new individual if enabled to develop into a baby. There are some who would, usually for religious reasons, object to this analogy. I respect but do not share their views. There is a timeline during which a gamete becomes an embryo, a fetus, a baby in utero, a newborn baby to a growing person. We should not ignore the unpleasant reality that, in practice, not all persons are given the same status within society. Senior politicians and religious leaders are accorded a special status, not because they are more valuable as a person but because of the position that they have achieved in society and their importance to the wellbeing of that society. If we apply this utilitarian approach to cell, tissues or persons, we have to accept a gradualist view of their status.

In relation to ES cell research, further inconsistencies have evolved as the debate has become ethically more confusing. UK regulation puts specific conditions on licences that relate to ES cell derivation that do not apply to research on embryos for other purposes. In the US it is acceptable to pay women to donate eggs from the treatment of others but not to pay women to donate eggs for research. In the UK it is not acceptable to pay women for eggs for either purpose. In many countries, embryo based research has been banned. In others there is inconsistency in the legislation with research permitted on post-implantation embryos that have been aborted but not on pre-implantation embryos. Elsewhere, such as the UK, research on both pre- and post-implantation embryos is permitted but the related legislation and regulation is different with a greater protection given to the pre-implantation embryo than to the post-implantation embryo. The ethical basis upon which such decisions are being made is muddled and would benefit from a review. This should start with the accepted general ethical principals of the medical research not with the political and media hype that surrounds embryos. Legislators should also be aware that prohibition does not stop research. It just directs the interested scientists to work in countries where there is permission. This may be an appropriate pragmatic approach by politicians who do not wish to challenge the minority groups that are fundamentally opposed to any research involving human reproduction but it only benefits the politicians.

The UK has the major advantage that there is clear legislation defining permitted activities related to embryo research (www.hfea.gov.uk). This provides protection against legal challenge and gives a secure framework within which research can progress. However the consequence of the regulatory burden associated with the legislation is that the work required to achieve the necessary permissions and oversight can be as great as the scientific challenges. In that respect the relationship between the clinician and scientist is critical.

In the IVF clinic, the link between the clinical embryologist and the gynecologist is the key to a successful clinical service. This is based on mutual respect and an understanding of the professional roles of each party. The clinician relies entirely on the good practice of the embryologist to produce viable embryos. The embryologist relies on the clinician to take the legally required consents. UK legislation provides that there is a single individual Person Responsible (PR) who takes overall responsibility for ensuring that everyone in the unit complies with the HFEA Code of Practice. Whilst the courts have agreed that this requirement cannot expect the PR to have direct oversight of both laboratory procedures and clinical practice, it is expected that protocols are in place with which all members of the team must comply. Failure of any member of the team to comply could result in imprisonment for the PR. A similar condition exists for embryology research. Whether the PR is the scientist or clinician, absolute trust between the professionals is essential. Undertaking research that needs an HFEA licence is thus not taken lightly.

How can clinicians be given incentive to participate in research that requires the donation of embryos? There must be recognition of the role of the clinician and inclusion of the necessary financial resources to support the work required in taking consent from patients. IVF clinicians have been challenged because of a perceived conflict of interest between their role as both doctor and researcher. This is not a new problem in medical research. It is addressed by the approved procedures for obtaining consent which take this into account. In the IVF clinic it can be managed realistically by ensuring that different staff members talk to the patients about research and treatment. The role of both the clinician and embryologist must be acknowledged. This enforces the view that the work has included an appropriate dialogue between the clinician, embryologist and researcher. Failure to show mutual trust and respect within the team gives an open door to those who want to stop such research.

The UK government has passed legislation that permits embryo research. Studies both in the UK and elsewhere have demonstrated that patients are willing to help by donating surplus embryos for research including ES cell derivation [Bjuresten and Hovatte, 2003; Bangsboll et al., 2004; Choudhary et al., 2004; Parry, 2005; Hammarberg and Tinney, 2006; Haimes et al., 2008]. IVF clinicians are willing to take the responsibility for obtaining consent under the required regulation. Scientists are developing the methodology needed for the reliable derivation of therapeutic grade ES cell lines. Legislation does not stop scientific progress. It just determines where it will happen.

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