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Consent: need for guidelines to reflect local conditions

Letter

Lipworth W, Irvine R & Morrell B. 2009

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SIR — As you point out in your Editorial (*Nature* 460, 933; 2009) on the distribution of human cell lines, withholding scientific material from the broader research community contravenes the basic norms of science. We do not believe, however, that standard international consent guidelines for donors are the solution to this problem and suggest that these should instead be devised on a local scale in collaboration with ethics committees to facilitate tissue distribution.

Far from research being “hindered by restrictions from donors” as you suggest, people are generally willing to donate tissue for research, and even to give open-ended consent to unspecified future applications. This willingness is underpinned by donors’ faith in medical research and in their right to protection and confidentiality; the assumption is that their tissue will be used only for ‘ethical’ research. But problems can arise, for example over whether consent covers the proposed usage (at present there are many different models of consent, ranging from specific to general) and when and how tissue should be discarded (K. Aalto-Setälä *et al.* *PLoS Biol.* 7, e1000042; 2009).

The answers may not always be obvious, and ethics committees (in collaboration with donors or their representatives) need to take into account the kind of tissue involved as well as the demographics and potential vulnerability of the donor or donor community, to judge the acceptability of the research proposal.

None of this precludes distribution of tissue in the name of scientific progress, nor should it if the wishes of donors are to be respected. However, it does challenge any unqualified presumption among researchers about access to human material; it also calls into question the ethical acceptability of using internationally standardized consent forms, as recommended in your Editorial. Rather, we would argue for international standards to ensure that tissue distribution is not thwarted by ethics committees, accompanied by a plurality of local approaches to obtaining consent.

This strategy would address the problems you outline, while demonstrating respect for moral decisions made by individuals and groups and preserving donors’ trust in biological medicine.