GENETICS

HOW CAN WE KNOW?

14.12.2006 3 COMMENTS

A recent paper in Nature reported

> Tissue samples were obtained from one of the following sources: Asterand, Pathlore, Tissue Transformation Technologies, Northwest Andrology, National Disease Research Interchange and Biocat. Only anonymized samples were used, and ethical approval was obtained for the study from Ärztekammer Berlin and the Cambridge Local Research Ethics Committee. […] Human primary cells were obtained from Cascade Biologics, Cell Applications, Analytical Biological Services, Cambrex Bio Science and the Deutsches Institut für Zell- und Gewebeersatz.

How did "Ärztekammer Berlin" or "Cambridge LREC" evaluate ethical performance of these companies? Or did anonymity automatically guarantee ethical research? Or is it just a formal requirement to mention ethics? Or …?

3 THOUGHTS ON "HOW CAN WE KNOW?"

Lisa

14.12.2006 AT 18:34

As someone who teaches informed consent for anatomical donation for transplantation and research, and serves as an expert witness/consultant on legal cases involving informed consent, the above comment is of interest to me.

Typically, research facilities and companies using human derived samples of tissue, be it from living or non-living donors are supposed to go through extensive IRB approval for their studies and in addition have solid Tissue Sharing agreements with the organization (s) providing the samples who also should have gone through an IRB approval and demonstrate sound Standards of Operations (SOP's) in place that are regularly QA'd for compliance. The sharing agreement should have language in place regarding ethial practices related to the consent and procurement of such samples. I can not comment on any of the practices of the above mentioned companies as I do not have first hand knowledge from working with them. What I can say however, is that my overall experience in this area has uncovered disturbing examples of laxity (and in some cases pure negligence) in monitoring the pratices by which these samples are consented for. There needs to be better oversight, monitoring and regulations specific to non-living donors and their NOK for protection under the CFR regs on informed consent and IRB requirements under the Office for Human Subject Research Protection.

admin

15.12.2006 AT 19:13

Lisa, thank you for commenting on my rather polemic question. All I can say, that I have also seen quite nice SOPs (which are even more vital for these companies) but having also bought samples in the past, I even do not know what the company told the donor and how he or she is being refunded. There might be also quite different rules in non-industrialized countries.

Lisa

2.02.2007 AT 02:09

I would like to converse with you more on the topic of tissue sharing agreements and communication with donors but am having trouble entering comments in this field as the authenication code provided doesn't seem to take and my comments disappear. if you get this would you email me directly at xxx@xxx.xxx? Thanks.

COMMENTS ARE CLOSED.