How IRBs make decisions: should we worry if they disagree?

Sharon Kaur

There is at present, far too little empirical research into the actual decision-making process of Institutional Review Boards (IRBs) and it is sobering to be reminded by Robert Klitzman’s article that while theoretical debates might rage and prove fertile ground for new theories and better ways of approaching research ethics; ethics committee members must try to make sense of these concepts and apply them in very practical situations.1 Klitzman provides important insights into the way IRBs approach questions about undue influence and coercion, and unsurprisingly, the results suggest that there is a lack of consistent standards both between and among IRBs.

However, the fact that IRBs grapple with these issues and that they invoke lively discussions among members who proffer different opinions; and that they struggle to come to decisions should not on its own be viewed negatively. IRB membership should reflect as much as possible, the diversity of the communities in which the research is carried out, and this will inevitably result in members coming to the review process with different ideas about coercion and undue influence. What is significant is whether the decisions taken by IRBs are consistent and coherent given the similarities and differences of the communities in which the research is being carried out.

One of the suggestions put forward is that regulators might provide further guidance as to the definitions of undue influence. It is contended that this risks not only creating the potential for more interpretive confusion, but at the other end, risks creating an inflexibility which might not translate fairly into complex social situations. The key would thus appear to be in providing IRB members with sufficient training in order to provide them with the tools they need to participate in meaningful discussions. They should be able to engage with one another in a discourse that is both coherent and easily accessible to all members, but which is at the same time sufficiently rich to encompass the needs and interests raised by cross-cultural, international, multicentre clinical trials. Therefore, although they might and should continue to hold different views about notions such as ‘undue influence’, their decisions will be well reasoned and coherent.

Competing interests None.

Provenance and peer review Commissioned; internally peer reviewed.

Received 18 September 2012
Accepted 19 September 2012

J Med Ethics 2012;0.
doi:10.1136/medethics-2012-100965

REFERENCE
How IRBs make decisions: should we worry if they disagree?

Sharon Kaur

*J Med Ethics* published online October 17, 2012
doi: 10.1136/medethics-2012-100965

Updated information and services can be found at:
http://jme.bmj.com/content/early/2012/10/16/medethics-2012-100965.full.html

*These include:*

- **P<P**
  Published online October 17, 2012 in advance of the print journal.

- **Email alerting service**
  Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

**Notes**

Advance online articles have been peer reviewed, accepted for publication, edited and typeset, but have not yet appeared in the paper journal. Advance online articles are citable and establish publication priority; they are indexed by PubMed from initial publication. Citations to Advance online articles must include the digital object identifier (DOIs) and date of initial publication.

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/