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Time to untangle ethical review of genetic research

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By Professor Richard Ashcroft and Dr Ainsley Newson, Medical Ethics Unit, Imperial College London and London IDEAS Genetics Knowledge Park

It is well recognised that genetic research raises ethical issues, such as the implications of increasing geno-centrism in healthcare. However the research process itself has attracted less attention. Most, if not all, genetic research in the United Kingdom is reviewed by a NHS Research Ethics Committee. This review typically doesn't examine the 'big picture' ethical issues about research issues in general, but concentrates on important but lower profile issues such as consent, research governance, and the management of sample collections. Yet researchers are increasingly finding that this procedure places unintended obstacles in the way of otherwise uncontroversial research, prompting a call for critical examination of research ethics approval for genetic research.

A collaborative workshop between the six Government-funded Genetics Knowledge Parks (GKPs) was held in November 2003. It highlighted the common frustrations being experienced by researchers. First, there is a lack of clarity about how ethical issues should be managed. Research ethics approval is often complicated by:

- The overlap between clinical genetics and research, including research on rare conditions;
- Committees lacking a paradigm in which to debate research with an undefined end-point (e.g.: mutation identification);
- Difficulties in accessing and using sample collections - for example, should anonymous DNA samples previously been found not to have the relevant mutation subsequently be used as controls?;
- Questions as to whether consent for the storage of samples obtained from children should be re-obtained when they become competent; and
- Deciding whether informed consent is needed for large-scale genetic database projects

Further, there are problems in the review procedure itself. Research ethics committees are perceived as having a lack of familiarity with the nuances of genetic research. Review is often slow, unwieldy and complex, and researchers report they are often denied a forum in which to explain research proposals in more detail. The amount of paperwork involved, particularly for small family studies, certainly acts as a deterrent to establishing new research projects.

Despite the difficulties being experienced, those working in genetic research do not believe ethics approval should be abolished. Ethics approval gives researchers increased confidence that participants' research interests will be protected and also provides pragmatic benefits such as securing funding. Several changes are, however, required to move forward. First, the development of a genetics-specific research ethics committee needs to be considered. Second, both researchers and ethics committee members need to accept the need for further education. The GKPs are

collaborating to pilot and deliver new educational initiatives, which are planned for national roll-out during 2006. Third, as an interim measure, if there is no genetics expertise on a committee, an expert should always be co-opted to review those projects requiring specific expertise. Only once these changes are made will ethics committees be able to actively facilitate the ethical conduct of human genetic research.

Genetics Knowledge Parks:

- Cambridge Genetics Knowledge Park

- Life Gene Park, Newcastle

- London IDEAS Genetics Knowledge Park

- Nowgen: North West Genetics Knowledge Park

- Oxford Genetics Knowledge Park

- Wales Gene Park