



# Ethics Watch

## POLICY BARRIERS IN COHERENT POPULATION-BASED RESEARCH

### URLs for Web

Public Project in  
Population Genomics:  
[www.p3gconsortium.org](http://www.p3gconsortium.org)

The **Public Project in Population Genomics** (P3G) is a public, accessible, central internet repository for research tools and knowledge transfer. The P3G consortium has identified several roadblocks in the socio-ethical and legal issues that are reflected in current laws and research-ethics guidelines governing population studies. These barriers affect not only policy-making but also the tool-sharing that is necessary to both successfully achieve the aims (and investment) in such research, and to realize the potential health gain from these large-scale resources. Here we discuss some of the barriers for policy makers. The Ethics Watch article that will appear in the next issue of this journal (February 2006) will examine tool-sharing in the context of population-based research.

Political, real-time and linguistic barriers, although not often highlighted in discussions on population studies, are crucial. Within their electoral mandates, governments might not be in power long enough to see positive political return from longitudinal population studies, and this affects their support of such efforts. Large-scale projects require a long lead-time and considerable administrative energy to set up and organize, to say nothing of cooperation and coordination from a range of stakeholders. Moreover, political and researcher buy-in requires a shift in the language of public consultation away from the language of the 'project'. Long-term endeavours involve building resources — that is, knowledge-creation infrastructures for eventual research uses. They also aim to enable public health decision-making and priority setting, as well as the promised applications to genetic medicine. So, the language that describes and refines such resources should reflect closely their real nature and future use.

The second barrier is the current emphasis in socio-ethical and legal normative instruments on approaches that are associated with highly penetrant monogenic diseases. The result is an overemphasis on autonomy and privacy. Within a constantly changing legal landscape, there is a need for international best-practices and principles that are specific to population-based research so as to foster the inter-comparability of socio-demographic, epidemiological, genetic and governance data.

The third barrier is the gap between the socio-ethical issues as identified by experts and policy-makers (who often rely on public-opinion polls), and the way that the participants in these initiatives see themselves. The onus should be on regulatory groups and funding agencies to gauge a balance between acceptable and unacceptable strategies, which is developed by consultations between all relevant stakeholder groups, including the study participants.

Finally, these huge population-based initiatives involve unforeseeable and shifting research needs and opportunities. How can a prospective informed consent be obtained from participants and political bodies that provides appropriate protection for volunteers while not unduly constraining desirable research? P3G's International Working Group on Ethics, Governance and Public Engagement suggests that, where legislation is desirable, sunset clauses (which make the act or part of it expire after a certain date) should be used to ensure future review when necessary. Furthermore, a broad consent combined with independent, procedural mechanisms for continuing ethical review and governance is essential. Continual communication and transparency on the goals, on the right to withdraw and on the research uses of such resources is the obligatory response to public trust, public investment, and the continued endorsement and consent of participants.

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