

House of Lords Science & Technology Committee
Genomic Medicine Enquiry
Response from the Ethics and Policymaking Core (EPC) of the Centre de recherche en droit public, Université de Montréal

1. Introduction

1.1. The Ethics and Policymaking Core (EPC) of the Centre de recherche en droit public, Université de Montréal, is a research group dedicated to examining ethics and policy issues related to international large-scale population databases and other biobank activities. The EPC collaborates with the Public Population Project in Genomics (P³G) Consortium (www.p3gconsortium.org) and its International Working Group on Ethics, Governance and Public Engagement to create tools that will aid the harmonization of various aspects of biobank policy. It is funded by the Canada Research Chair in Law and Medicine, Genome Canada, Génome Québec and the Centre de recherche en droit public, Université de Montréal.

1.2. The EPC welcomes the opportunity to provide the Lords Science and Technology Committee with information regarding international collaborative efforts in the area of population-based databases and related biobanks.

2. Data Use and Interpretation

2.1. Collaboration is recognised as a significant driver in current practice of biomedical research. Examples include the Human Genome Project (HGP), the HapMap Consortium and Welcome Trust Case Control Consortium. In these collaborations, the data derived were available from a central resource (even in cases where the data was mirrored across resources, such as with the HGP). An alternative to a centralised resource is to enable different resources to share data efficiently and effectively. This is the model that the P3G Consortium follows. It does not advocate a single database for population-related data, as it acknowledges that population biobanks reflect the scientific and cultural diversity of those who they include as participants. Instead, P3G is dedicated to the dual scientific aims of optimising the design and conduct of *individual* biobanks as well as harmonising the design and conduct of activities *between* biobanks. It is well documented that no one population database will have the statistical power

to confirm all causal links between genes, health and environmental factors. By being able to share data from various biobanks, researchers will be more able to confirm their hypotheses. But in order to accomplish this, the data itself must be harmonised so that it can be shared across biobank platforms. The generic Data-SHaPER project is an example of a response to this need. Funded by P3G and other partners, including Generation Scotland, and with the collaboration of 17 international biobanks, including UK Biobank, the Data-SHaPER tool is a set of generic variables (primary units of analysis) that will be used to harmonise the data in existing and emerging biobanks. Such examples of international collaboration show that specific blocks in the research process can be examined and tools developed to address them, helping to drive the translation of basic data into clinical applications.

2.2. Another example of international collaboration has been the efforts of the EPC to create another tool for harmonisation, generic consent materials. With appropriate consents in place, data and samples can be shared across biobanks and with other researchers. Based on the consent materials of P³G-member biobanks, including Generation Scotland and UK Biobank, generic consent materials were created to assist existing and emerging biobanks to determine the key issues that should be raised with potential participants in biobank research, when seeking their consent to participate. These materials, as with any other tools developed by the P³G Consortium, are publically available on the P³G Observatory website at <http://www.p3gobservatory.org/welcome.do>. The EPC is now preparing generic access, material transfer and governance materials.

2.3. As noted above, both UK Biobank and Generation Scotland are contributing to and collaborating in these on international initiatives to aid the harmonisation and best practice of and between biobanks. If such prominent biobanks continue to participate at the international level, other biobanks from developed and developing countries may see the benefit and also work to share their resources with the biomedical community. This can only aid translational activities with the ultimate aim of improving population health through genomic medicine.