

Special points of interest:

- harmonizing and standardizing (p.2)
- Interviews (p.5)

Editorial

Dear GeneBanC friends

A warm welcome to the first GeneBanC newsletter of 2008. GeneBanC is gathering momentum as the first series of papers has been published as a result of research during the first year of our project. The partners of GeneBanC have also been very active in presenting their results at international conferences. As GeneBanC is a multidisciplinary project the first fruits of our project cover different domains that touch the reality genetic biobanks: public health, governance, law and medical ethics. This newsletter and the GeneBanC website provide full details of these activities.

For 2008 GeneBanC will be active with some workshops on the different societal aspects of genetic biobanking. An important step in our project this year is the organisation of a Stakeholders' Conference in Brussels in November, where we want to bring together individuals and organisations to discuss issues of biobanking in an open and fair manner. This process of stakeholder engagement will be particularly important in the second stage of GeneBanC in order to confront our research findings with the opinions of the many stakeholders and see how they can serve as a basis for further debate.

As GeneBanC is coming at cruising speed the number of contacts with other biobank players in the field is rapidly increasing. We recently met at the European Commission with the coordinators of other E.C. funded projects that

are focussing on likewise topics. Besides GeneBanC will be represented at P3G: Public Population Project in Genomics. (see article Georg Lauß and Herbert Gottweis in this newsletter) P3G is a non-for-profit international consortium to promote collaboration between researchers in the field of population genomics. It has been launched in order to provide the international population genomics community with the resources, tools and know-how to facilitate data management for improved methods of knowledge transfer and sharing. Its main objective consists in the creation of an open, public and accessible knowledge database. The motto is transparency and collaboration.

Kris Dierickx



By Kris Dierickx, Co-ordinator GeneBanC (Centre for Biomedical Ethics and Law, K.U.Leuven)

In this issue

On the following pages we bring you again more information on the GeneBanC-project.

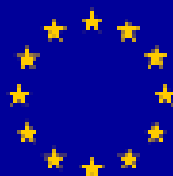
On page 2 Georg Lauß and Herbert Gottweis describe the Population Project in Genomics (P3G) and the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI). These are examples of sharing data and samples on an international level.

On page 5 Marcus Griffin and Darren Shickle provide information about interviews they have conducted with scientists responsible for eighteen biobanks in six countries: England, Denmark, Latvia, The Netherlands, Sweden and

Wales. In addition they also conducted interviews with some of the people involved with ethics/governance committees associated with biobanks.

If you are doing research on the ethical, legal and social aspects of biobanking, or if you have useful information for this newsletter, feel free to contact us. GeneBanC-greetings,

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Recent developments in harmonizing and standardizing international biobanking activities:



Georg Lauß



Herbert Gottweis

During the last decade, we have witnessed a significant expansion in collecting and processing of human biological samples, and of related informational data. In the literature, such practices and their institutional embeddings are labeled with the term biobank. Biobanks are repositories of human biological specimens, and it is frequently claimed that they will have significant strategic importance for genetic research, clinical care and future treatments.

Following the rapid progress in genomics research of humans and their ancestors, biomedical and health research has expanded from the study of rare monogenetic diseases to common, multifactorial diseases. (1) Elucidation of complex disease aetiology is challenging because diseases are caused by a large number of small, often additive effects, representing the sum of the consequences of genetic predisposition, lifestyle and the environment. Therefore an ideal Biobank complements tissue material with, serum samples, blood lymphocytes, primary cell cultures, laboratory data, clinical results, histopathological results, family anamnesis, therapy data and its follow ups. (2)

However, even large collections will lack the statistical power to study complex diseases for the next 15-25 years if they work on their own. (3) The solution for this problem is to foster sharing of data and exchange of samples on an international level. This contribution will report developments in that field. The first section will introduce the Population Project in Genomics (P3G). The second section will give an overview about the most recent European initiative: The Biobanking and Biomolecular Resources Research Infrastructure (BBMRI).

Setting biobanking standards on an international level: The case of P3G

Biobank governance is increasingly characterised by its deterritorialised, transnational/global character. One of the first prominent examples of efforts for internationalization of biobanks was the Public Population Project in Genomics (P3G). (4)

The Public Population Project in Genomics (P3G) is a non-for-profit international consortium to promote collaboration between researchers in the field of population genomics. It has been launched in order to provide the international population genomics community with the resources, tools and know-how to facilitate data management for improved methods of knowledge transfer and sharing. Its main objective consists in the creation of an open, public and accessible knowledge database under the motto transparency and collaboration.

International Working Groups, each composed of a multi-disciplinary team of investigators, have been formed to promote knowledge exchange between cores related to a specific IWG theme, in order to assure that synergies are created between the cores. The IWG will identify the primary research questions to be developed by the cores, monitor progress and provide external information or advice to the cores. IWGs will focus on core research activities, milestones, and deliverables for fulfilling P3G's strategic objectives and oversee the content to be included in the P3G knowledge-base.

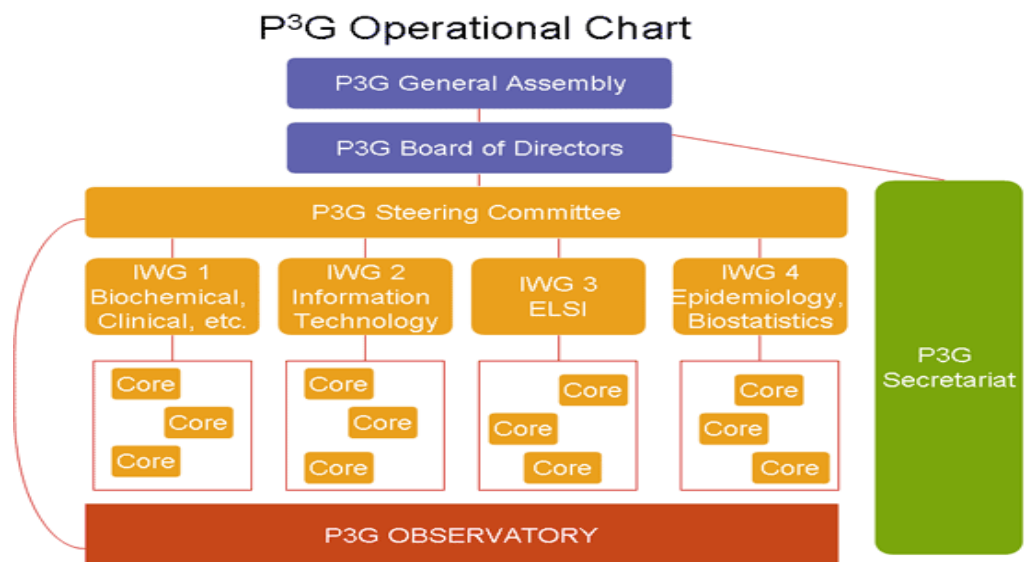


Figure 1. Source: <http://www.p3gconsortium.org/>

P³G Cores are key work units of P³G, focused on specific issues related to biobanks, with full-time personnel having expertise on specific issues related to biobanks, such as methodologies for: integrating data: validating new technologies for biochemical analyses or genotyping; research into public engagement into relevant governance and ethics questions, analysis methods in population genetics related to merging data from biobanks collected using different study designs, etc. Thus, the Cores have an important research focus, as opposed to providing services (such as genotyping).

P³G is designed to have a modular structure to allow flexibility in adding multiple P³G Cores. It is expected that some countries will want to create P³G Cores with similar themes (ie. epidemiology, or, ethics): given the complexity and different approaches that can be developed for conducting analyses across biobank/cohort studies, more than one Core having similar research themes can be established.

Preparing a European Model for the harmonization of biobanks

BBMRI: Aims and Project- Organisation

For several years, there was discussion and preparation going on the EU level to tie the various biobank projects, the leading protagonists, infrastructures and strategies together in a common effort. (4) These efforts led to Project “Biobanking and Biomolecular Resources Research Infrastructure” (BBMRI).

Building on achievements of previous and ongoing initiatives like the P³G consortium, the WHO and the OECD initiative on a global network of Biological Resource Centers BBMRI brings together 55 institutions from 16 European countries in the way that is presented in figure 2.

The following goals were presented at the ‘Kick of Meeting’ from February 10- 12 in Cambridge UK: (a) to develop the plan to integrate existing quality controlled biobanks, biomolecular resources and enabling technologies into pan-European biomedical research infrastructure; (b) to provide a concept for its operation and codes of conduct for European biobanks, particularly considering the different technical standards and types of health care integration currently applied; (c) to evaluate the heterogeneous European ethical and legal frameworks and find solutions how to implement a pan-European infrastructure; (d) to elaborate sustained funding and financing solutions for this key resource.

BBMRI: Building a biobank- hub- structure in Europe

To overcome current limitations and to cover the needs of the scientific community a Pan-European resource will be constructed by linking the individual efforts mentioned above: Key components of BBMRI are thus comprehensive collections of biological samples from different (sub-) populations of Europe, which should be linked with continuously updated data on the

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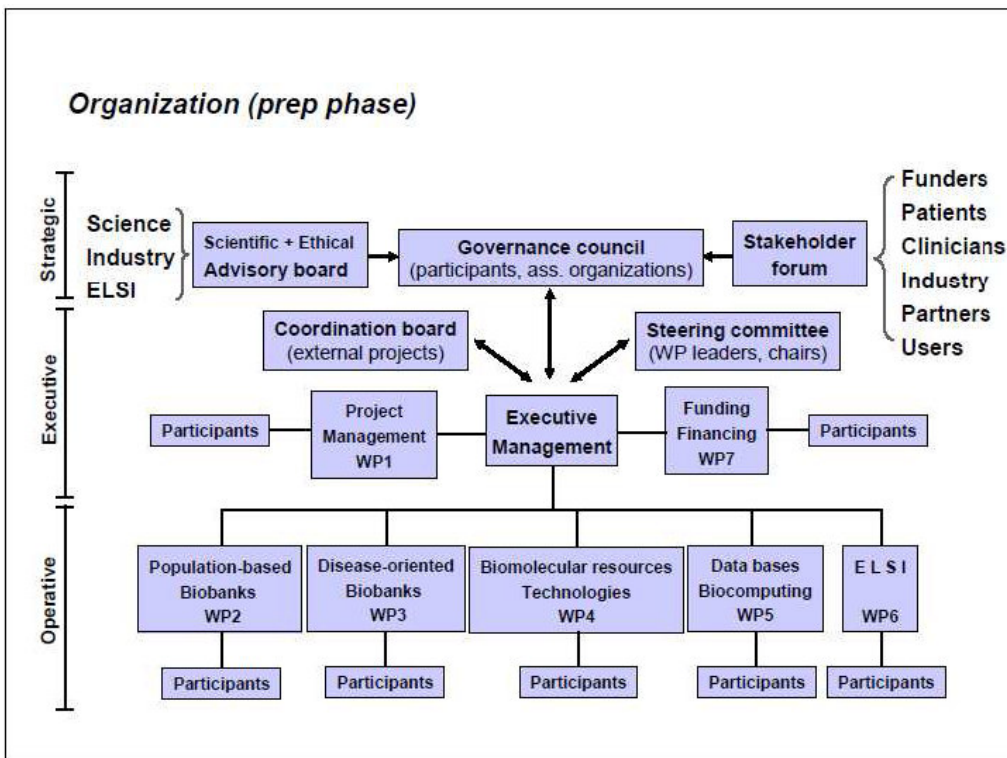


Figure 2: Grant Agreement for Combination of Collaborative Project and Coordination and Support Actions.

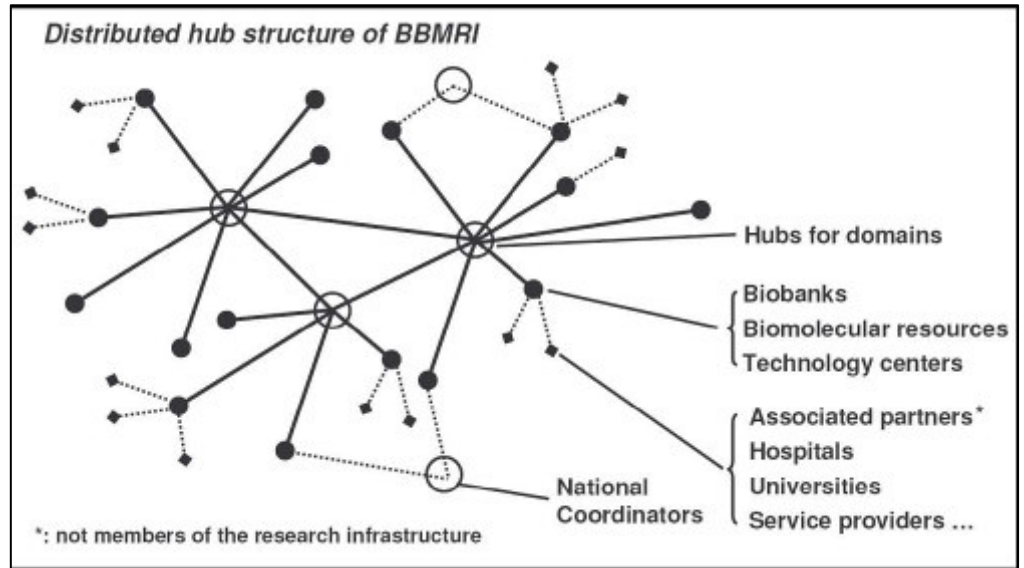


Figure 3: Biobanks, biomolecular resources and technology centres are members of BBMRI and connected to their specific hub. Partners, who are not members, may be associated with members. In addition to domain-specific hubs there are national coordinators to address issues specific for EU Member States, such as legislation or national funding systems.

“Therefore, the format of BBMRI should be a distributed hub structure in which the hubs coordinate activities, including collection, exchange and analysis of samples and data for the major domains.”

health status, lifestyle and environmental exposure of the sample donors. This can only be achieved in a federated network of centres established in most, if not all, European Member States (5) Therefore, the format of BBMRI should be a distributed hub structure in which the hubs coordinate activities, including collection, exchange and analysis of samples and data for the major domains. (figure 3)

The biobanks, biomolecular resources and technology centres, which are members of BBMRI, are associated with their specific domain hub. Furthermore, a variety of public or private partners (e.g., universities, hospitals, companies), which provide biological samples, data, technologies or services, may be associated with certain BBMRI members. This structure provides great flexibility so that new members and partners can be connected at any time and that it can be easily adapted to emerging needs in biomedical research.

The IT-infrastructure which employs federated database architecture and grid computing technology will integrate the complex network of hubs, members and partners into a single virtual infrastructure. (5) Hubs will be coordinated and directed by an executive management, which is supported by a governance council as well as by a high-calibre advisory board and receives input from the stakeholder forum to guarantee clear responsibilities as well as open and transparent decision-making processes.

Standardizing access to biomaterial and connected- data

The distribution of biomaterial and supplement- data creates the need to develop a widely shared access policy that has to take into account different legal frameworks, IC procedures, confidentiality and efficiency standards. Over the last decades scientists had to decide if they approve or disprove request for sharing stored samples, on a case by case basis, more or less on their own. Standing in the cold, in front of their freezers, their judgement was based on rather subjective non-harmonized criteria.



A scientist in front of a cryo- freezer.

A report on Biological Resource Centers issued by the OECD states that "the operational guidelines governing the essential functions of Biological Resource Centers (BRCs) are diverse, particularly with regard to access to biological data and materials and their exchange and distribution. These rules and regulations are national and international, are issued by many different authorities, have very different degrees of enforceability and pertain to the many and varied roles of BRCs: health and safety requirements for humans, animals, plants, and the environment ethical considerations, intellectual property rights protection, import-export regulations and technical standards." (6)

Outlook

Herbert Gottweis is member of the BBMRI consortium and responsible for societal aspects in the BBMRI ELSI team. Georg Lauß is individual member of P3G. The outcomes of these projects will have crucial impacts for the post-genomic era of the 21st century in Europe as well as on a global scale. From inside these arenas we will follow the developments towards harmonization and standardization of biobanking and bio-molecular resource centres. From these experiences we hope to derive important insights, which will help to draw lessons for governance issue in biobanking and the governance of the "life-sciences" in general.

By Georg Lauß and Herbert Gottweis (Life-Science-Governance, Institut für Politikwissenschaft, Wien, Austria)

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www.p3gconsortium.org

Governing Biobanks – What are the challenges? Conference announcement

From 23 to 26 June 2008 an interesting conference is organized at the St. Anne's College in Oxford (United Kingdom). The aim of this conference is to explore some of the complex and challenging issues that emerge from the governance of biobanks. The intention is to reflect on the internal governance mechanisms that have been developed for biobanks and to understand the rationale and principles that underpin them. There is also a need to explore the global governance mechanisms that should be put in place to facilitate harmonised systems for data-sharing at a global level, whilst at the same time protecting the interests of all stakeholders.

Some of the questions that the conference seeks to address are:- What are the appropriate governance mechanisms for data-sharing in a global civil society? What is the role of law and national regulators in global research? Is informed consent possible, in a world where datasets are shared or networked across national boundaries, and biobanks are used as resources by many different researchers for multiple different projects over many years? What is the relationship between individual privacy, family rights or interests and the 'public interest'? How should the perspectives of research participants be incorporated into governance structures? How do the different paradigms or research models of clinical and statistical research affect the ways in which biobanks are, or should be, governed? Who are the key actors in the regulation of biobanks at the national level, and how do they exercise power? What accountability mechanisms currently exist, or should be put in place? How should the benefits of genomic research be distributed individually or globally?

More information on : <http://www.ggd.org.uk/index.cfm?fuseaction=events.content&cmid=28> or <http://www.functionalgenomics.org.uk/sections/activities/2008/Kaye/info.htm#programme>



Practical, legal and ethical considerations in establishing a biobank



Darren Shickle



Marcus Griffin

The aim of Workpackage 2 is to examine the practical, legal and ethical considerations in establishing a biobank. The four main objectives are (a) to describe the practical, legal and ethical issues faced by population and small scale biobanks and how these have been addressed; (b) to examine the advantage and disadvantages of classical biobanks (disease specific case control studies) versus population biobanks (prospective); (c) to inform scientists and policy makers when making decisions as to whether to develop future retrospective versus prospective biobanks; and (d) to improve governance arrangements by better understanding the problems faced by existing biobanks.

Data is collected via interviews with the lead researcher responsible for the biobank. The interviews will examine practical, legal and ethical considerations in establishing and maintaining the biobank/register. The following questions are being addressed: What ethical scrutiny has been given to the biobank when it was established? What governance arrangements are in place monitoring the Biobank? How were the public/patients consulted before establishing the biobanks? Are they involved in the on-going governance arrangements? How are subjects being recruited? What has the response rate been? How is informed consent being sought? How have the future uses of the biobank been defined? How is confidentiality being maintained? What measures are in place for data protection? Who has access to the database? How have intellectual property rights been addressed?

The initial intention was to conduct up to thirty interviews across Europe, with a sampling frame based on size of biobank and whether they were prospective cohorts of case-control studies, as follows: four large prospective population biobanks, six smaller prospective cohort studies, twenty small disease specific case control registers.

So far interviews have been conducted with thirteen scientists responsible for eighteen biobanks in six countries: England, Denmark, Latvia, The Netherlands, Sweden and Wales. In addition we are also conducting interviews with some of the people involved with ethics/governance committees associated with biobanks. There are a number of high profile national prospective biobanks that have attracted considerable media attention and were subject to analysis by academic lawyers, ethicists and social scientists. One of the most

prominent biobanks that we have visited so far is UK Biobank. UK Biobank is a prospective longitudinal cohort study, recruiting 0.5 million people aged 40-69 from across the UK, looking at common complex diseases of middle-old age. It is funded by the MRC and Wellcome Trust and has 10000 recruits as of July 2007. Recruitment will take place over 3 to 4 years at centres set up across the country first in urban and then in more remote areas. The centres will be assessing over 100



people a day. Phenotypic measurements are taken as well as blood samples for DNA analysis. Data will be released to scientists at the appropriate time intervals for particular studies and tenders for specific studies will put out at the appropriate time by the MRC. Both private and public researchers will be encouraged to utilise the bank. It is estimated that the bank will cost £1-2 million each year to maintain and set up costs are estimated at around £60 million.

A number of countries are attempting to establish national biobanks. For example, in addition to UK Biobank, we have also visited the National Latvian Biobank in Riga, which is operating on a far smaller budget than its UK equivalent. However, there are also less publicised biobanks and so we wanted to interview scientists from both large and smaller prospective population biobanks. For example, we have conducted interviews about two such important biobanks in Rotterdam.

The Rotterdam Study is a single centre prospective cohort study that started in 1990 in Ommoord, a suburb of Rotterdam, among 7,983, men and women aged 55 and over. In 2002 another 3,011 participants (55 years of age since 1990) were added to the cohort. The main objective of the Rotterdam Study is to investigate the prevalence and incidence of and risk factors for chronic diseases in the elderly. The chronic diseases of interest are cardiovascular, neurological, locomotor and ophthalmologic diseases. Baseline data collection was performed from October 1990 to July 1993. Since then all participants have been re-examined every 2-3 years. Morbidity and mortality is registered through general practitioners practices.

The Generation R Study is a prospective cohort study from fetal life until young adulthood in a multi-ethnic urban population within Rotterdam. The study is designed to identify early environmental and genetic causes of normal and abnormal growth, development and health from fetal life until young adulthood and also aims to contribute to the development of strategies for optimizing health and healthcare for pregnant women and children. The children will be followed until young adulthood. In total, 9778 mothers with a delivery date from April 2002 until January 2006 were enrolled in the study. Of all eligible children at birth, 61% participate in the study.

Our interview sample incorporates other biobanks involving birth cohorts or children. For example, we have collected data on the Danish Birth Cohort, and later in 2008 we will include the Born-in-Bradford Cohort.

We have also included a prospective cohort biobank that is looking at risks from occupational exposures. The Airwaves Study was established to examine potential risks associated

with a new communication system being used by the British police.

In comparison disease specific case control biobanks, have tended to attract even less attention by ethicists, lawyers and social scientists.



Collectively across Europe there will be far more samples contained within these retrospective biobanks, than the large population cohorts.

Many of these case-control biobanks started out as simply case series of samples collected

by individual institutions or small groups of clinicians, and were generated from clinical investigations rather than an intention of establishing a resource for genetic research.

The UK National Malignant Hyperthermia Muscle Tissue and DNA bank is a collection that was started in 1971. People with an adverse reaction to anaesthesia suggestive of malignant hyperthermia are referred to the clinical investigation service in Leeds. Muscle tissue is tested and blood taken for DNA analysis. Patients with a positive result for malignant hyperthermia are recruited for the biobank. With permission other family members are investigated. The aim is to develop a DNA test for Malignant Hyperthermia for patients prior to receiving a general anaesthetic.

The Erasmus MC Cancer Biobank uses residual tissue from procedures carried out within the Erasmus Medical Centre in Rotterdam, the bank was formally instigated in 2002 but there is an archive of material dating back to the founding of the centre in the 1960's. There are between 18 and 20 000 frozen samples and an archive repository of 90-120 000 samples a year.

The ethics and regulatory frameworks were very different when such long standing biobanks were first established. Interviewees responsible for these older biobanks explained to us how they have to reconcile the lack of ethical consideration and donor participation at the start of the collection with the much more rigorous environment today. Some interviewees were uncomfortable with using older samples within their collections for research.

As part of the process of identifying potential interviewees, we also discovered examples of retrospective 'healthy' population cohorts, which were based on data collected many years previously. For example, one of the biobanks that we examined in Copenhagen, was based on data collected by the Danish Military Draft Boards as far back as 1943. Potential military recruits that were excused because they were overweight have subsequently been contacted to study obesity and morbidity.

Within our initial thinking, we recognised that it would be important to distinguish large national population cohorts such as in the UK or Latvia, from smaller regional/city cohorts. However, our interviews have also covered case-control biobanks of very differing size. The first biobank that we interviewed is examining rare dental malformations and is based within our own University in Leeds. However, other case-

“So far interviews have been conducted with thirteen scientists responsible for eighteen biobanks in six countries.”

control biobanks are very large, and also may not be disease specific, for example some covered a range of cancers.

The Wales Cancer Bank aims to collect samples of tumour, normal tissue and blood from all patients in Wales who are undergoing an operation to remove tissue where cancer is a possible diagnosis. The aim is to help understand the molecular mechanisms involved in cancer and work towards the selection of optimum targeted treatment for individuals. The Wales Cancer Bank is currently collecting a variety of tumour types from seven hospitals across Wales. The biobank also contains blood samples from a control population (similar age and resident in the areas as the patients).

While many case control biobanks are focused on cancers, other diseases are also represented within the biobanks that we have interviewed so far.

The GRIP (Research in genetically isolated populations) Biobank was established in 1995. The biobank is examining several complex genetic disorders including diabetes melli-



tus type 1 and 2, Parkinson's disease and Alzheimer's disease in a genetically isolated population in the Southwest of the Netherlands. Using municipal records and genealogical databases of this isolated population of 20,000 residents, it has been possible to link most of the patients of each disorder to a common ancestor.

It can be difficult for a single institution to collect sufficient samples to conduct research on rare diseases. Thus, increasingly, there are initiatives to establish databases to document where samples for rare conditions are held in other institutions. These networks facilitate pooling of scarce material across a network.. In 2002, TuBaFrost was set up in the first instance to provide a bigger repository for research platforms from which to investigate rarer cancer types and subtypes. It was an initiative of the Erasmus MC Department of Pathology and the EORTC Data Centre in col-

laboration with a number of cancer research institutes united in the OECl in different European countries. The objective was to create a virtual network via a web-based database connecting the constituent institutes frozen tumour banks (including the Erasmus MC one). The resource was to be available to the scientific community as a whole.

Whereas TuBaFrost was a means of researchers finding who to contact for a request to share samples, networks are also forming which will bring together samples to a single location. OnCoreUK Has been running for about three years and evolved from a previous project run by NTRAC (National Translational Cancer Network) which was never completed. It has three funders; the Department of Health, the Medical Research Council and Cancer Research UK. Its aim is to collect biopsies and blood samples from post-diagnosis cancer patients for future biomedical research.

As part of the NCRI Confederation of Cancer Biobanks, it aims to provide a UK-wide sample base for cancer research. Samples are collected via The National Cancer Research Networks through which OnCoreUK hopes to collect a broad range of cancer types and sufficient quantities of samples to facilitate high quality research.

In order to build even larger research platforms some biobanks, in addition to expanding to form networks, are now coming together to form international 'networks of networks'. This has brought about unique problems and unique solutions to ethics and governance over multiple jurisdictions. Through a framework 5 project the Tubafrost team employed a law firm specialized in European medical affairs to look at legislation in EU countries and set up a code of conduct. The code basically stated that you had to treat whatever sample you were using according to the protocols of the country of origin.

The role of the National Biobank Programme in Sweden was to network Universities in Sweden by providing funding to facilitate sharing of expertise in running biobanks rather than to explicitly develop a network to share samples. Although increased collaboration in devising

protocols for how to process and store samples, for example, as well as in using shared expertise in developing guidelines on ethics and governance issues, may also lead to increased research collaboration.

Where funding comes from also appears to have an effect on the governance and ethical scrutiny of a biobank. Projects that are government funded or through charities seem to spend more time on public consultation and pay more attention to governance and ethical considerations. Whereas those that are funded in house appear to have less consultation with the public, in some cases they have none and ethics and governance tends not to be by separate and independent bodies.

Some of the more recently established biobanks have given thought to independent forms of ethics review and governance, including representation from the public or patient groups, although in many cases such oversight committees only seemed able to make suggestions, rather than require changes in the way the biobanks were operated. Many biobanks had management committees made up from the scientists who 'owned' the biobank, or if there were other external members they still had a science background.

Regulatory frameworks within countries often reflect the relationship between researchers, government, and the public. For example in the Netherlands and in Denmark, the public are much more trusting of scientists and government which leads to access to data and consent protocols which would be unacceptable in more suspicious environments where various scandals and hostile media have conspired to create mistrust in the public and much tighter regulation of researchers.

Often we observed from researchers in less tight regulatory frameworks almost a more relaxed approach towards public participation or the dangers involved in the use of confidential information and informed consent. While the system seems to work well, at least from the perspective of scientists and regulators, there may be potential problems for the functioning of biobanks in such environments if public trust was damaged by research scandals or a feeling of being taken for granted.

Larger, well-funded and more recently established biobanks were more likely to have given thought to and obtained legal advice about intellectual property right issues. Most interviewees were very open in talking about the ethics and governance of their biobank. In only

one case, did an interviewee decline to discuss the intellectual property issues relating to their biobank because the subject was considered too sensitive.

For most of our interviewees intellectual property issues have been a low priority. In some cases they had given thought to it and decided that it was unlikely that there would be any commercial interest or any money to be made out of their research. Others would have welcomed commercial interest in their biobank, but have managed to attract little or none. The main priority for many interviewees seemed to be merely the continuance of their research. Thus they were happy to have commercial partnerships provided it helped fund their laboratories and staff, and were not overly concerned about ownership of patents etc.

Those biobanks receiving funding from government bodies decided to have the widest possible access to their databases because legal advice had said that they have to. Consideration had been given to whether it would be feasible to restrict or give preferential access to local researchers or those from the public sector. But again, legal advice was that it would be difficult to enforce such restrictions.

Also such restrictions would be difficult to put in place in practice, as deciding who has priority or who pays more/less for access is a political hot potato. Smaller biobanks organised by small groups of researchers, did tend to be more restrictive in access to their data/samples, usually by requiring that they were collaborators with any external research utilising their biobank thus forwarding the interests of the founding researchers.

There appears to be more effort made towards IP issues in the UK compared with the biobanks we have interviewed in the rest of Europe, this maybe because of the more market-based culture, compared with the rest of Europe which still sees academic research as more of a service to the community. Interviews so far have been held in Northern Europe, and so over future months there are plans to use our contacts in Poland and Italy to conduct further interviews in Central, Eastern and Southern Europe.

By Darren Shickle and Marcus Griffin, Academic Unit of Public Health, University of Leeds (U.K.)

“Projects that are government funded or through charities seem to spend more time on public consultation and pay more attention to governance and ethical considerations.”

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The last few years have witnessed an important expansion of collection and processing of human biological samples and of the related information data. Biobanks are huge repositories of human biological specimens and have a strategic importance for genetic research, clinical care and future treatments. Genebanc is a Specific Targeted Research Project (STREP) funded by the European Commission in the Sixth Framework Programme. This research project aims to investigate the ethical, legal and social issues of three types of biobanks: classical banking, population banking and forensic DNA databases.

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informed consent for the collection, storage and use of biological materials

The creation and management of biological banks raise profound ethical and legal issues concerning informed consent, confidentiality, biological material (and related information) ownership, access to the bank, commercial interests and discriminatory use of research results. In a recent publication Corinna Porteri and Pascal Borry have focused on informed consent for the collection, storage and use of biological materials for research purposes in the health field. The most important ethical aspect in the collection, storage, and use of biological materials for research purposes is the maintenance of a strong link between use of biological materials and donor's consent. This means that the person concerned should be well informed on the essential elements of the present and foreseeable future uses of his/her biological materials, and that he/she should have the right to choose to participate in the research project, as well as in the creation of the biobank. Moreover, he/she should have the possibility to put limitations to the potentially unlimited use of the materials.

In the recent contribution the authors propose two different informed consent forms. The first is for the use of biological materials within a well-planned single research project; and the second is both for the storage of biological materials in a biobank set up at a local level – such as are those set up in university departments, hospitals and scientific institutes – and for the use of stored samples. The proposed model can be a useful guideline for the development of specific informed consent forms to be used by researchers for the collection, storage and use of biological materials. It can also be a good tool to let the potential donors know which information, guarantees and opportunities they can request from researchers.

By Corinna Porteri (IRCCS 'Centro S. Giovanni di Dio – Fatebenefratelli', Brescia, Italy) and Pascal Borry (Centre for Biomedical Ethics and Law, K.U.Leuven, Belgium), A proposal for a model of informed consent for the collection, storage and use of biological materials for research purposes, Patient Education and Counseling (2008).