GeneLibrary Ireland

[ An essential new resource to underpin health research in Ireland ]

Supporting research
Developing understanding
Improving health
Making a difference
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A BRIEF OVERVIEW

Setting the scene
The Health Research Board (HRB) in Dublin and the Research and Development Office (RDO) in Belfast set up an expert group to examine the merits and feasibility of establishing an all-island ‘biobank’. In 2003, the group agreed that such a databank was both desirable and feasible, and proposed that the idea be pursued. As this would be a resource for the common good, the name proposed is GeneLibrary Ireland. The group presented a detailed feasibility study during 2004 (available for reference on the HRB website at www.hrb.ie). This contained an outline protocol, which will be further developed if the project is approved and funded.

Why do we need GeneLibrary Ireland?
Scientists need to study information and samples from large numbers of people in their investigation of the complex and sometimes subtle effects that genes can have on our health. This information is not always easy to get and collecting it often costs a lot of scarce time and money. The aim of GeneLibrary Ireland is to have a common resource of samples, which researchers can use to study the role that different genes play in sickness and health. This will be a powerful and valuable resource for health research on the island of Ireland which, fuelled by the human genome project, will lead to discoveries about the causes of disease, new diagnostic tests, new drugs and even new cures.

Why is it important?
This resource would help health research to achieve results more quickly, and to be more efficient and cost effective. Some diseases are more common in certain parts of Ireland, and the genetic background of the Irish population varies from East to West. The all-island aspect of this project would allow researchers to investigate these effects and take account of them in their studies.

What will the library contain?
The proposed library will have DNA and blood samples collected from 10,000 volunteers throughout the island of Ireland, the results of a detailed medical examination (e.g. information about their height, weight and heart function) and answers to a questionnaire on aspects of their lifestyle and environment. This combination of both samples and health information will make the archive especially useful.

How will the information be collected?
Collecting the 10,000 samples and health information will not take more than two years. This would be the largest, most detailed survey of Irish health ever undertaken, and in itself would be a valuable exercise, generating important baseline information.

People who donate samples to the library will benefit directly by receiving a comprehensive medical examination, the results of which can be sent to them and, if they wish, also to their GP; as is usual with such donations, volunteers will not otherwise be paid.
What about privacy?
All records in the library will be irreversibly ‘anonymised’, making it impossible for anyone to link records to individuals. Making the records anonymous in this way is necessary for legal and ethical reasons, to address concerns about privacy and data security; it also means that the information can be made freely available to researchers, and the resource can be used to its fullest extent.

How will the information be used?
The resource will serve as a large ‘control group’, providing essential health information that will be representative of the population as a whole. Scientists studying a particular disease will need to collect samples only from people with the disease, which they will then be able to compare with samples from the library. In this way, the resource will be an important and enduring part of the health research infrastructure on the island of Ireland.

Who will be able to use GeneLibrary Ireland?
Researchers on the island of Ireland, and researchers elsewhere with whom reciprocal arrangements exist, will be allowed to access the facility, provided that: they submit their research plan to scientific and ethical committees for approval, bear the cost of any DNA analyses, and add their results to the main database when they have published their research. In this way, the library and all its users will benefit from each study.

Who will manage it?
GeneLibrary Ireland will have a board of management, a scientific steering committee, and an executive subcommittee responsible for day-to-day management.

How much will it cost?
It is estimated that GeneLibrary Ireland will cost approximately €3 million to establish, and between €100,000 and €150,000 to maintain each year.

Who is recommending it?
This proposal was prepared by an expert group, which was convened by the HRB (Dublin) and the RDO (Belfast). Dr Bernadette Herity, Emeritus Professor of Public Health Medicine and Epidemiology in UCD, was Chair of the group. For details of the group and their terms of reference, see the Appendix. A full copy of the group’s feasibility report is now available in PDF format at www.hrb.ie.
THE CONTEXT

The growth and benefit of research

We are poised at the start of a revolution in our understanding of the causes of illness and disease. The successful sequencing of the human genome and the discovery of new tools for studying DNA, mean that we can now begin to explore the important role genes play in sickness and in health, across a whole range of diseases, from Alzheimer’s and arthritis to coronary heart disease and cystic fibrosis, from diabetes and obesity to schizophrenia and skin cancer.

We can now, for instance, begin to investigate why some people’s genetic make-up means they are more likely to develop colon cancer. Why it is that some men, and not others, develop prostate cancer. And why certain infections make some people susceptible to rheumatoid arthritis. We can also begin to ask whether some people’s genetic make-up means that they might react badly to a particular drug, or whether their tumour will respond well to chemotherapy.

Ultimately, these studies will lead to new understanding, new diagnostic tests and, it is hoped, new and more effective vaccines and drugs.

A current study on schizophrenia in Ireland, for example, has discovered a gene that is strongly associated with schizophrenia. Described as the most important research finding for this condition in 20 years, this discovery is the result of a collaborative study of Irish families affected by schizophrenia carried out by research teams in Dublin, Belfast and the USA. It was the homogeneous nature of the Irish population that attracted the researchers to take their samples from the Irish population.

Other such studies, attempting to explore the complex interplay between genes, lifestyle, diet and the environment and the role of genes in disease susceptibility and reactions of drugs, are now under way on the island of Ireland and elsewhere. They are part of the growing body of bio-medical research that, powered by developments in genetics, is shedding light on the causes of disease. Ultimately, these studies will lead to new understanding, new diagnostic tests and, it is hoped, new and more effective vaccines and drugs. Already we are seeing the first fruits of such work in new bespoke treatments tailored to match patients’ genetic backgrounds.
THE RATIONALE

To investigate the complex and sometimes subtle effects that genes can have on our health, scientists need to study information and samples from a lot of people. Typically, they will study a group of people who have the same disease or condition of interest. They will compare these results with samples from a group of ‘normal, healthy’ people – what scientists refer to as a ‘control’ group. By comparing information from each of these groups, scientists hope to find out more about the genes involved and how they are affecting or influencing the disease.

The size of the control group will vary depending on the type of study and the disease being studied. Normally, it is not difficult to recruit people with a specific disease, or their relatives, to take part in a study; they can see the direct benefit to themselves, to a family member or to the community. Recruiting people to participate in the control group can be more difficult, more time consuming and expensive.

For instance, recent international research involving the HRB, Trinity College Dublin and the National Institutes of Health in the US examined the genetics of spina bifida and other neural tube defects. They successfully collected DNA samples from 1,000 healthy people (the control group) and some 400 people with a neural tube defect. This is an excellent sample group but, due to the nature of the sample collection, the samples taken from the 1,000 strong control group were only given for use in this particular study and no other.

GeneLibrary Ireland, with DNA samples donated by volunteers across Ireland, together with information about their health, will provide ready access to samples for the type of research mentioned above. It will mean that individual studies would no longer need to spend scarce resources on large recruitment campaigns; researchers could conduct their studies more quickly and efficiently and avoid duplication. This more efficient and cost-effective method will benefit research and the results will be of benefit to everyone. GeneLibrary Ireland will become a crucial part of the long-term infrastructure of biomedical and health research throughout the island of Ireland.

GeneLibrary Ireland will be a national reference library of donor samples and health information acting as a common control-group for a wide range of studies by health and bio-medical scientists.

The concept in practice

The last few years have seen tremendous growth in the field of biomedical research, fuelled by the successful sequencing of the human genome. Collections of DNA and tissue samples, the raw material for this research, have also grown. Many of these collections are referred to as ‘biobanks’, and there are now a great many of them worldwide. Biobanks vary tremendously in size, content and design. There are those that contain samples from people with a particular disease, for instance, or samples from the population at large; some are commercial ventures, some are small private collections, and some are national projects.
The Irish scene

A growing number of sample collections for specific diseases (known as ‘case collections’) already exist in Ireland:

- Belfast City Hospital has collected samples from people with osteoporosis and multiple sclerosis.
- University College Cork (UCC) has samples donated by families affected by Crohn’s disease.
- The largest disease collections are those now being established by the Dublin Molecular Medicine Centre: this collaborative initiative involving TCD, UCD and the Royal College of Surgeons in Ireland, together with Dublin’s six teaching hospitals, will investigate the role of genes in several diseases (those currently proposed are: prostate cancer [with the support of the Irish Cancer Society], coronary heart disease, schizophrenia and inflammatory bowel disease), and will collect some 3,000 samples for each disease studied.
- In a separate initiative, TCD’s Institute of Molecular Medicine aims to establish a control group of DNA samples from a random selection of Irish residents.

These sample collections are essential for the specific research initiatives mentioned; they are not intended to be an all-island resource. Clearly, an archive like GeneLibrary Ireland will greatly assist and complement these initiatives, and would itself benefit from their expertise and experience to date. A large-scale all-island gene library would be designed and managed from the outset to make the best use of resources and to ensure that the archive would be used as widely as possible. For this purpose, creating one large shared resource of samples allied to medical, lifestyle and environmental information will be more valuable and powerful than establishing several small sample collections.

The International Scene

The world’s largest biobank is currently being established in Britain: *Biobank UK* is a £50 million project, funded mostly by medical charities and research bodies, that is part biobank, and part health study; it will comprise samples and medical information from 500,000 middle-aged volunteers, whose health will be monitored for thirty years.

A more controversial project is the *Icelandic health sector database*. Called Decode, this is a commercial venture, introduced following a referendum, comprising samples and medical records for nearly all of Iceland’s population (residents must formally opt out of the project); a 12-year licence has been awarded to the company involved, which, significantly, will be permitted to sell its research findings.

National biobank projects have been established in other countries too, for example in Sweden, Singapore and Estonia, and smaller local projects in Quebec, Sardinia and elsewhere. Many biobanks exist that are related to specific population groups (for instance, Jewish communities and African-Americans), or to certain diseases (such as the Irish neural tube defect study mentioned on page 5).
DEVELOPING GENELIBRARY IRELAND

Creating an Irish GeneLibrary is an important opportunity to add tremendous value to existing health research, to avoid duplication of scarce resources and, for a small outlay, to conduct a major survey of our health status. A variety of approaches could have been taken.

For example, the approach taken by Biobank UK is a ‘cohort’ study, samples are collected and then people are monitored over a 30-year period to see who succumbs to disease. This will undoubtedly contribute significantly to medical research and understanding of disease. The cohort approach involves:

1. Monitoring 500,000 people over 30 years
2. Spending 17 years to establish the collection and conduct the follow up
3. Collecting specific records, which yield thorough information. The records will not be anonymous which causes legal and ethical complications and limitations.

The approach to GeneLibrary Ireland involves creating, with the co-operation of 10,000 volunteers, an all-island ‘control’ group representative of the entire island. This common control group of samples will be irreversibly anonymised. This approach means:

1. Samples will be used for multiple studies
2. The bank of samples will be established more quickly, cheaply and easily
3. Initial results will be available in three years
4. Detailed clinical information will be collected
5. Because of the irreversible anonymisation of data, fewer ethical and legal questions will arise.

The bank of samples can also be:

1. Made freely available to researchers (because data is irreversibly anonymised)
2. Used to study genes associated with various diseases such as obesity
3. Used to establish the baseline health status of the population
4. Used to study social and regional variations in health status.

GeneLibrary Ireland is an all-island initiative: several studies have found that gene frequencies vary across the country from east to west, possibly reflecting the extent of mixing between the earliest Mesolithic settlers and later arrivals. This trend may explain why some conditions, such as coeliac disease, are more common in some regions than in others.

This geographic variation must be taken into account in genetic studies of disease susceptibility. The best way to do this is to ensure that GeneLibrary Ireland covers the island of Ireland. An all-island sample library can also be used to ascertain whether associations found in other countries are also valid here.

Finally, collecting samples and health information from 10,000 people across the island of Ireland is in itself an important survey of the country’s health status, and the largest that will ever have been undertaken. For this reason, it is recommended that extra funding be allocated for some initial genotyping analysis on all the information collected. This would allow researchers to compare, for instance, the measurements, history and genetic background of the most obese and least obese people in the population.
The process of developing the library

GeneLibrary will contain medical history and other relevant information, together with blood and DNA samples, from 10,000 people aged between 25–74 years of age. These people will have been invited to take part in the project and, in addition to contributing to this important national resource, will themselves benefit directly by receiving a comprehensive medical examination, the results of which can be sent to their GP. They will not otherwise be paid for their contribution.

The library will be an almost inexhaustible resource for research; with careful management, the DNA extracted from one blood sample can be sufficient for numerous studies, allowing scientists to study many thousands of genes in detail.

It has been calculated that, to be useful, the library will need samples from 10,000 donors. To reach that target, international experience suggests that 20,000 people will need to be invited to participate (selected from the electoral registers), of whom about 14,000 might agree to be interviewed and, of those, it is hoped, 10,000 will agree to participate.

Collecting the data to create GeneLibrary Ireland

The simplest and most efficient way to reach potential donors will be to draw a sample of households from the electoral register and send invitations to the residents there. Notices and publicity in local and national media at this time will help to explain the project. (Households could be sampled in 20 areas, both urban and rural, across the island of Ireland). Interviewers would then visit and invite the residents to participate.

Where people are willing to participate, the interviewers obtain their consent and go through a questionnaire with them (this will include questions relating to medical history, and smoking and alcohol intake, and perhaps their use of the health services). The participants will then be invited to attend a local centre where they will have a medical examination by a nurse and provide blood and urine samples.

The medical examination will cover:

> Eyesight
> Hearing, in those aged over 60
> Tooth count
> Physical measurements (height, weight)
> Blood pressure
> Blood sample
> Respiratory function
> Urine sample
> Body impedance (an indirect measure of body water and fat content)
Vascular function, in those over 40

Autonomic function, reflexes, in those over 40

Resting ECG, in those aged over 40

Energy expenditure

Physical activity

Measuring energy expenditure (by doubly-labelled water) is expensive, but it is recommended that perhaps five percent of the participants should be given this test, as this information will be especially valuable for studies on obesity, and in designing public health measures to reverse the growing obesity epidemic.

One sample of blood will be analysed immediately for plasma lipid and glucose levels, and a further six samples from each participant stored for later analysis. Urine samples are to be analysed for albumin (an early indicator of high blood pressure damage) among other things.

Participants will receive their results within a matter of weeks, and they can also opt to have the results sent to their GP. This is important, as it is expected that the resting ECG, for instance, will detect a number of previously undiagnosed cases of probable heart disease. Once any follow-up queries have been dealt with, the records will be irreversibly anonymised. Participants can withdraw from the project up to the point where the records are anonymised.

The process continued...

The fieldwork, interviews and collection of samples can be outsourced to a survey agency (or consortium of agencies), with a full-time project manager reporting to the sub-committee. To avoid any conflicts of interest, researchers on the steering committee will step down if they become involved as contractors in the fieldwork or laboratory analyses. It is anticipated that a small university-based team will manage the project’s two-year set-up phase with an annual budget of €200,000 (for three full-time staff and overheads).

The 10,000 samples collected initially will be a long-term resource for the future. Each 10ml EDTA blood sample will yield at least 300µg of DNA. With modern PCR techniques, DNA can be replicated and should not run out. Provision for this should be built into the GeneLibrary Ireland. For the most efficient use of the samples, it is recommended that samples are stored and genotyped by the same laboratory. Researchers or scientists who use the library and have special requirements can be given aliquots, or sub-samples, to analyse in their own laboratories.
ADDRESSING THE CONCERNS

Collecting information and samples from people, using these samples in research studies, and storing them long-term, all raise important ethical and legal issues, such as obtaining informed consent to the initial testing and the subsequent research, the participant’s right to decide who should be informed of the test results, and the management of access to the samples.

The protocol devised for GeneLibrary Ireland will adhere to the highest possible standards and guiding principles, since it is essential that the project is acceptable to all interested parties and stakeholders, including potential donors.

There is currently no legislation in Ireland or Britain governing this area, although a number of draft guidelines are being considered. Internationally, it is generally agreed that irreversibly anonymised collections lead to fewer legal and ethical issues. For instance, if researchers subsequently discover that a participant carries a newly identified gene for susceptibility to some disease, and if that participant’s identity is known, the question arises: should the participant be notified? Such complications mean that biobanks with identifiable records are difficult and costly to use and to administer, and the samples cannot be made freely available to researchers. For these and related reasons, the HRB and the RDO recommend that the records in GeneLibrary Ireland be irreversibly anonymised.

Privacy and confidentiality

The following safeguards will be in place to ensure that participants’ privacy and confidentiality is respected:

> Before potential participants give their consent, the project will be thoroughly and clearly explained to them. An individual will have the right to refuse to participate.

> The consent form will be designed to the best possible standards and will explain the potential use and storage of the clinical data and samples and the irreversible anonymisation process.

> No information will be gathered and no samples will be taken unless the consent form has been signed, and if someone does not consent, then no sample would be taken. Those who agree to take part can indicate on the consent form whether they wish to be notified of the initial medical examination results, and whether they want those results sent to their GP.

> All ethical and legal issues will be addressed.

> The information will be irreversibly anonymised once participants have been given the results of their tests, and it will be impossible for anyone to link the records to the individuals.

> Participants can withdraw from the project, up to the point where records are irreversibly anonymised (after which withdrawal will not be possible).

> Independent data security experts in Northern Ireland and in the Republic of Ireland will review the process.
Irreversibly anonymising the information will address any privacy, data protection, legal and ethical issues – for instance, there is no question of police or forensic services or insurance companies gaining access to the samples and information. This means that GeneLibrary Ireland will be easier and cheaper to administer than approaches taken elsewhere.

The project is designed first and foremost for the common good of the people of Ireland and Northern Ireland. The project will not be driven by commercial considerations.

**Access and use of GeneLibrary Ireland**

Researchers on the island of Ireland, and researchers abroad with whom there is a reciprocal agreement on sharing samples and clinical data, will be allowed access to the resource, provided they cover the costs of their analyses and give something back, in the form of their results. Specifically, prospective users must:

> Submit their research plan to the scientific committee for approval
> Bear the cost of any DNA analyses
> Add their results and data to the main database, after they have been written for publication.

In this way, the library and all its users will benefit from each study.
TIMESCALE AND COSTS

It is estimated that it will take two years to establish the library and database, including nine months of fieldwork (initial interviews with participants, followed by physical examinations at 20 centres around Ireland).

Timescale:

> Recruitment of staff, training, finalising protocol months 1—9
> Fieldwork (interviews, collecting samples, etc.) months 9—18
> Sample banking, genotyping and analysis months 16—24

Equipment, infrastructure and costs

The estimated cost of this two-year phase would be approximately €3 million, to include management, interviews and medical examinations, and the initial analysis of the 10,000 samples. Annual running costs have been calculated at about €100,000—€150,000 per annum.

These costs are based on current prices, and include maintaining the collection, storing, retrieving and providing aliquots of samples, and data management. Estimates compare favourably with costs incurred by other surveys elsewhere.

These are relatively modest costs, given the tremendous long-term benefit, which this resource will bring to Irish health research.

The fieldwork will not require much new infrastructure: the survey agency can recruit and train interviewers and nurses, and rent temporary space in local community centres and hospitals, and trailers equipped as mobile examination centres could be used in rural areas. The detail of these costs are itemised in the table below.

It is recommended that there is no need to establish a new facility to host the GeneLibrary Ireland but that the extraction and banking of samples should be outsourced to a commercial or academic facility.
Schedule of indicative costs

<table>
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<th>Items</th>
<th>Cost €</th>
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<tr>
<td><strong>Project management (two years)</strong></td>
<td></td>
</tr>
<tr>
<td>Three salaries for two years:</td>
<td>320,000</td>
</tr>
<tr>
<td>Expenses and equipment:</td>
<td>80,000</td>
</tr>
<tr>
<td><strong>Survey and fieldwork (12 months)</strong></td>
<td></td>
</tr>
<tr>
<td>40 half-time nurses:</td>
<td>840,000</td>
</tr>
<tr>
<td>40 half-time interviewers:</td>
<td>760,000</td>
</tr>
<tr>
<td>Expenses, equipment etc.:</td>
<td>650,000</td>
</tr>
<tr>
<td><strong>Laboratory analyses:</strong></td>
<td>300,000</td>
</tr>
<tr>
<td><strong>Extracting and banking DNA:</strong></td>
<td>150,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€3.1 million</strong></td>
</tr>
</tbody>
</table>

The blood plasma samples must be stored in freezers at minus 80ºC. The DNA can be stored either in solid format (i.e. on FTA paper) at room temperature, or frozen in solution at minus 20ºC. These options need to be further explored, as freezers with automated retrieval of specimens are currently expensive. This is the only stage of the project likely to require investment in infrastructure.

Storage can be rented on any secure site that has backup power supplies and facilities for connecting an alarm to the telephone network. DNA aliquots (samples) can be transferred to whichever laboratory is used for the routine genotyping. The GeneLibrary Ireland management centre will maintain the main database of clinical and genetic data. Full-time staff will be needed to manage the database, but there are no special infrastructure requirements.

Management of the resources

GeneLibrary Ireland will have a Board of Management, a scientific steering committee and an executive subcommittee responsible for day-to-day management.

Custodianship of GeneLibrary Ireland and control of the use of the samples will rest with a Board of Management that is representative of all interested parties, with an independent chair and a number of independent members, with no vested interest or conflict of interest.

The Board will be responsible for GeneLibrary Ireland’s central administration and for storage arrangements for the data and the biological samples. The Board will establish a scientific steering committee to develop policy and to oversee applications from researchers wishing to use the resource. This management structure will be developed and implemented by the HRB and the RDO in consultation with interested parties and individuals.

The steering committee of researchers would decide GeneLibrary Ireland’s strategic direction and prepare a detailed protocol; a smaller, executive sub-committee would be responsible for day-to-day management.
CONCLUSION

It is clear that, for a relatively small outlay, Ireland could acquire a very valuable and powerful resource for health research. GeneLibrary Ireland has real potential to become a crucial part of the long-term infrastructure for biomedical and health research in Ireland, with the result that:

> Individual studies will no longer need to spend scarce resources on large recruitment campaigns,

> Researchers are able to conduct their studies more quickly and efficiently and avoid duplication.

This more efficient and cost effective approach will benefit research and the results will be of national benefit. On this basis the HRB and RDO propose that funding GeneLibrary Ireland should be advanced as a priority.

GeneLibrary Ireland has real potential to become a crucial part of the long-term infrastructure for biomedical and health research in Ireland.
APPENDIX: EXPERT GROUP – MEMBERS AND TERMS OF REFERENCE

Dr Bernadette Herity*  Emeritus professor of Public Health Medicine and Epidemiology, UCD
Dr Ruth Barrington  Chief Executive, HRB, Dublin
Prof Bob Stout  Director of R & D for the Health & Personal Social Services, Belfast
Prof Hugh Brady  Dept of Therapeutics and Medicine, UCD
Dr Michael Boland  Irish College of General Practitioners
Prof Leslie Daly  Dept of Public Health Medicine and Epidemiology, UCD
Prof Frank Kee  Dept of Epidemiology and Public Health, QUB
Dr Michael Boland  Irish College of General Practitioners
Prof Leslie Daly  Dept of Public Health Medicine and Epidemiology, UCD
Prof Frank Kee  Dept of Epidemiology and Public Health, QUB

* Chair and convenor  ** Secretary to group

The group’s terms of reference were to assess and report on the following:

> Scientific rationale for an all-island biobank for research into the genetic causes of disease

> Ethical and legal issues involved, and how these might be addressed

> Governance arrangements

> Conditions under which researchers would be given access to samples in the biobank

> Cost of establishing the biobank over a five-year period and how costs might be met

> Numbers of volunteers needed, and their distribution by age, sex, and geography

> Number and nature of the biological samples to be collected and stored

> Baseline data collection

> Arrangements for handling and analysing the data and for statistical support

> Possible location(s) for the biobank

> Feasibility of incorporating existing collections of biological material into the biobank

> Most productive relationship between an Irish biobank and Biobank UK