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A Review of International Biobanks and Networks: Success Factors and Key Benchmarks

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Biobanks and biobanking networks are involved in varying degrees in the collection, processing, storage, and dissemination of biological specimens. This review outlines the approaches that 16 of the largest biobanks and biobanking networks in Europe, North America, Australia, and Asia have taken to collecting and distributing human research specimens and managing scientific initiatives while covering operating costs. Many are small operations that exist as either a single or a few freezers in a research laboratory, hospital clinical laboratory, or pathology suite. Larger academic and commercial biobanks operate to support large clinical and epidemiological studies. Operational and business models depend on the medical and research missions of their institutions and home countries. Some national biobanks operate with a centralized physical biobank that accepts samples from multiple locations. Others operate under a "federated" model where each institution maintains its own collections but agrees to list them on a central shared database. Some collections are "project-driven" meaning that specimens are collected and distributed to answer specific research questions. "General" collections are those that exist to establish a reference collection, that is, not to meet particular research goals but to be available to respond to multiple requests for an assortment of research uses. These individual and networked biobanking systems operate under a variety of business models, usually incorporating some form of partial cost recovery, while requiring at least partial public or government funding. Each has a well-defined biospecimen-access policy in place that specifies requirements that must be met—such as ethical clearance and the expertise to perform the proposed experiments—to obtain samples for research. The success of all of these biobanking models depends on a variety of factors including well-defined goals, a solid business plan, and specimen collections that are developed according to strict quality and operational controls.

Introduction

Biobanking involves the collection, processing, storage, and dissemination of biological samples and their associated clinical data and information, organized in a systematic way. A well-managed biobank is a critical prerequisite for high-quality biomedical research. Recent advances in the tools and technology of molecular biology and genetics have increased the demand for well-annotated, properly preserved specimens. In response to that demand, biobanks have been established on several continents within the past dozen years, and more are in development. This review outlines the approaches that 16 of the largest biobanks and biobanking networks in Europe, North America, Australia, and Asia have taken to collecting and distributing human research specimens and managing scientific initiatives while covering operating costs. This information may be of interest to groups considering, or currently establishing, biospecimen repositories. Several different operational and business approaches have been taken, with varying degrees of success in terms of long-term sustainability and meeting scientific goals. "Success" depends on many technical, ethical and legal, and financial factors. The trend toward international collaboration in biobanking and biospecimen utilization makes it important to understand these factors.

The biobanks covered in this review do not consider biospecimens to be tradable commodities; therefore, they

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all operate as not-for-profit entities. Further, to avoid exorbitant biospecimen fees that might inhibit research, the banks discussed do not attempt to recover their full operating costs from investigators who request samples. Rather, they depend upon government and/or charitable funds along with reduced fees for researchers to enable biospecimen collection, storage, processing, and dissemination. Most of these repositories accrue specimens from cancer patients and handle them so as to enable a variety of downstream analyses. Additionally, the biobanks reviewed tend to have similar access policies, requiring information about the experiments to be performed and the funding thereof, justification for the specimens requested, and ethical handling of the human materials. Beyond these commonalities, there is little consensus between the featured biobanks regarding whether to store samples in central or distributed locations; whether to incorporate nongovernmental donations into the economic model; whether to offer derivative samples such as purified nucleic acids in addition to tissue and blood products; and whether to require that unused biospecimens or research results be returned to the banking institution.

Biospecimen Collection Characteristics

The 16 biobanks and networks chosen for this review represent a geographically diverse set of organizations with varying approaches to collection and dissemination. Table 1 summarizes the general characteristics for the 16 biobanks in this review. With respect to the population from which biospecimens are collected, two of the repositories obtain biospecimens from the general population and one centers on patients with rare diseases. However, most of the biobanks under consideration—13 of 16—are disease-based and focus on cancer. This is a natural outcome of the fact that cancer treatment frequently entails surgical excision of the diseased tissue, and generates material upon which, under proper consent procedures, research may be conducted without physically endangering the patient. The majority of these biobanks perform general collection, that is, they procure and process biospecimens in a manner that produces samples suited to a variety of technological research platforms. We refer to these collections of tissues with no specific research projects in mind as "general" in Table 1. Two of the repositories collect biospecimens exclusively for pre-

Table 1. Biobanks Summarized in This Review

	Name	*Scope*	*Collection*	*Storage*	*Biospecimens*
1	Australasian Biospecimen Network (Australia)	Cancer	General, (project-driven on request)	Federated	Tissue, blood, DNA, RNA, tissue microarrays, cell lines
2	Australian Prostate Cancer BioResource	Prostate cancer	General	Federated	Tissue, blood, tissue microarrays, cell lines
3	BancoADN (Spain)	Various	General	Centralized	DNA, blood, cells
4	Canadian Tumor Repository Network	Cancer	General	Federated	Tissue, blood, saliva
5	Centro National de Investigationes Oncologicas Tumor Bank Network (Spain)	Cancer	General	Federated	Tissue
6	Chernobyl Thyroid Tissue Bank (Russian Federation)	Thyroid cancer	General	Federated	Tissue, blood, DNA, RNA, tissue microarrays
7	Confederation of Cancer Biobanks (UK)	Cancer	General	Federated	Tissue, blood, DNA, RNA
8	Cooperative Human Tissue Network (USA)	Cancer	Project-driven	Federated	Tissue, blood, tissue microarrays
9	EuroBioBank	Rare diseases	General	Federated	Tissue, DNA, cells
10	Kathleen Cuningham Consortium for Research into Familial Breast Cancer (kConfab; Australia)	Breast and ovarian cancers	General	Centralized	Tissue, blood, tissue microarrays
11	onCore UK (UK)	Cancer	General	Centralized	Tissue, blood, DNA, RNA
12	Singapore Tissue Network	Cancer	Project-driven	Centralized	Tissue, blood, DNA, cell lines
13	Tubafrost: European Human Tumor Frozen Tissue Bank	Cancer	General	Federated	Tissue
14	UK Biobank	Various	General	Centralized	Blood, urine
15	Victorian Cancer Research Tissue Bank (Australia)	Cancer	General	Federated	Tissue, blood, RNA, DNA, tissue microarray
16	Wales Cancer Bank	Cancer	General	Federated	Tissue, blood

defined research endeavors. We refer these to as "project-driven" collections. Another repository typically procures biospecimens for general use, but may be contracted to perform project-driven collections.

Most of the biobanks under consideration include numerous sites at which samples are stored. In these cases of "federated" collections, researchers generally may query a single database encompassing all of the participating sites. Five of the 16 sites rely on a centralized physical repository. For example, the US National Cancer Institute (NCI)'s Cooperative Human Tissue Network (CHTN) is a virtual biobank that functions under a federated system on a demand and supply model. Investigators request particular samples and the NCI coordinators at the CHTN meet the request from a variety of sources. The banks are evenly divided as to whether they offer researchers access to purified nucleic acids extracted from biospecimens they have accrued; half do and half do not.

Economic Models

Each of the biobanks discussed adheres to the principle that human specimens should not be commercialized; thus, each is a nonprofit entity. The consensus among these banks is that operations require funding beyond what is gained from cost-recovery systems, that is, the fees charged to researchers to access biospecimen samples and data. Table

Table 2. Economic Parameters of 16 Biobanking Programs

	Name	*Funding Sources*	*Price per Sample*
1	Australasian Biospecimen Network (Australia)	Government (Australia) and public/advocacy	Available upon request
2	Australian Prostate Cancer BioResource	Government (Australia), commercial, and public/advocacy	Partial cost recovery: A$185 for 20 µm of tissue sections A$30 for 0.5 mL of blood products A$100 per tissue microarray
3	BancoADN (Spain)	Government (Spain) and university	€1 per µg DNA for non-profit organizations €1.54 per µg DNA for commercial organizations
4	Canadian Tumor Repository Network	Government (Canada)	Available upon request
5	Centro National de Investigationes Oncologicas Tumor Bank Network (Spain)	Charitable funding, private and commercial donors	€15 per case, additional charges for nonstandard procedures
6	Chernobyl Thyroid Tissue Bank (Russian Federation)	Government (European Commission, USA, Japan)	No charge for specimens, but researchers may be charged for shipping or additional work on the part of the relevant Eastern European Institute.
7	Confederation of Cancer Biobanks (UK)	Collaboration between biobanks, each with its own funding sources	Cost recovery, fee-for-service
8	Cooperative Human Tissue Network (USA)	Government (USA)	Investigators pay a nominal processing fee for samples in addition to shipping. Slides and blocks to accompany frozen or fresh tissue specimens may be available for an additional fee.
9	EuroBioBank	Government (European Commission) and charitable	Varies by participating bank: processing and shipping fees apply
10	Kathleen Cuningham Consortium for Research into Familial Breast Cancer (kConfab; Australia)	Government (Australia) and public/advocacy funding	Academic Investigators: A$300 to A$1,500 per year Commercial entities: by negotiation
11	onCore UK (UK)	Government and public/advocacy funding	Partial cost recovery
12	Singapore Tissue Network	Government (Singapore)	Available upon request
13	Tubafrost: European Human Tumor Frozen Tissue Bank	Government (European Commission) and charitable	Provider negotiates directly with the requestor regarding cost compensation
14	UK Biobank	Government (UK) and charitable funding	Partial cost recovery
15	Victorian Cancer Research Tissue Bank (Australia)	Government (Victoria) and charitable funding	Non-profit entities: range from A$18 per H&E section to A$139 per paraffin block. Different scale for commercial entities
16	Wales Cancer Bank	Government (Wales) and charitable funding	Varies according to the type of sample requested

2 describes for each biobank the funding sources and price per sample (if available). None has implemented a cost-recovery program that fully covers all operating expenditures at this time. However, reliance on governmental and charitable funding varies, as does the degree of cost recovery. The overwhelming majority of these biobanking programs receive support from local and/or national governments. More than half—9 of 16—also depend upon private contributions. Only one does not receive any government monies to support its operations, but relies solely on charitable contributions and cost recovery. The approaches to cost recovery generally aim to defray a portion of the price of biobanking while avoiding fees so expensive as to inhibit research. These range from asking solely for researchers to pay sample transportation costs, to assessing transportation costs plus a nominal fee to defray biospecimen collection and handling, to models in which researchers compensate a greater portion of the burden the biobank incurred to collect, process, store, and transport the samples they request. Four repositories impose different cost-recovery rates for nonprofit research vs. commercial endeavors. Additional sample-processing services are offered by 4 of the 16 biobanks at a cost fully borne by the requesting researcher. It is worth noting that except for the UK Biobank, which is a population-based initiative, all of these biobanks are disease-based. Although data are not available to quantify costs over time, in general a disease-based biobank can expect to incur much higher costs during its initial development period, due to the necessity to invest large amounts of personnel effort, materials and equipment in establishing the collection. In contrast, population-based collections generally require smaller up-front investments but incur higher long-term costs due to the need for years of storage and other personnel and maintenance costs to preserve and analyze specimens until study goals have been completed.

Biospecimen-Access Policies

One of the major criticisms of biobanks is that specimens are collected and stored for lengthy periods before being used, delaying their productive use by researchers, and possibly delaying new discoveries and treatments for patients.

As summarized in Table 3, of the institutions evaluated, 14 have biospecimen-access polices or recommendations in place; 2, onCore UK and UK Biobank, are not yet disbursing biospecimens. EuroBioBank-access policies are member-bank-specific and not summarized here. Several policies were consistent throughout the 13 whose polices were evaluated: all require applicants to describe the proposed experimentation, specifying the desired biospecimens and accompanying annotation. All require that applicants have the expertise to perform the proposed experiments, which must use an established methodology; and all except Tubafrost indicate that applicants should verify that they have sufficient funding to complete the proposed studies. In addition, all the 13 institutions require requestors to provide evidence that the project has obtained ethical clearance and that applicants respect participant privacy by not attempting to identify individual biospecimen donors. They further specify that the biospecimens provided are to be used only for the proposed purpose and are not to be redistributed to others without written consent.

Several access policy models have been developed among the evaluated institutions. While most have internal panels to review applications, 4 indicate that applications undergo external review. Three national biobanks will supply biospecimens only to researchers in their own countries or to collaborators thereof. Three do not specify that statistical justification for the requested sample size be included with the application. Two biobanks require authorships on publications resulting from research conducted on biospecimens they have provided; 9 others request acknowledgment. Three institutions specify that they should be notified of any clinically relevant data so that patients may be informed; 6 indicate that experimental data either be deposited with the biobank or made publicly available. More than half of the repositories—9 of 13—anticipate that publications resulting from experimentation on the supplied biospecimens be lodged with them. Seven institutions request that applicants provide reports on the experiments being conducted; the timing of this varies, although the most common requests are for annual reports or a single report after completion of the study. Six of the 13 biobanks request that unused samples be returned to the bank.

Individual Biorepositories and Biobanking Networks

Australia

The *Australasian Biospecimen Network*[1] is a nonprofit organization funded through Australian governmental and public/advocacy organizations. It comprises 7 distinct cancer biobanks, each of which may store biospecimens. Collection and storage protocols are geared for broad use; however, project-driven prospective collection may also be conducted upon request. Researchers may access tissue, blood, purified nucleic acids, tissue microarrays, and cell lines. The price to obtain these items is not available online. Return of unused samples and any clinically relevant data is recommended.

The *Australian Prostate Cancer BioResource*[2] is a nonprofit organization funded through Australian governmental and public/advocacy organizations. It comprises 4 prostate cancer biobanks, each of which may store biospecimens. Collection and storage protocols are geared for broad, general use. Australian researchers or their collaborators may access tissue, blood, tissue microarrays, and cell lines, and are expected to return any unused portions as well as research results after completion of the study. A partial cost-recovery model is in effect such that 20 μm worth of tissue slice costs US$185; one-half milliliter of blood products costs US$30; a tissue microarray costs US$100.

The *Kathleen Cunningham Consortium for Research into Familial Breast Cancer*[3] (kConFab) is a centralized repository for tissue, blood, and tissue microarrays from breast and ovarian cancer families in Australia and New Zealand. This nonprofit biobank is funded by the participating national governments and public/advocacy groups. Shipping costs plus an annual administration fee of US$300 gives nonprofit research organizations access to tissue sections and associated data; higher fees, up to US$1,500, allow access to more epidemiological information and DNA from breast cancer gene carriers and their families. For-profit entities may access the same biospecimens and information at a negotiable rate. Return of unused samples and research results is expected.

The *Victorian Research Tissue Bank*[4] is a consortium of repositories in Victoria, Australia, offering cancer biospecimens

Table 3. Biospecimen-Access Policies of 16 Biorepositories

	Name	*Application review*	*National origin requirement*	*Justification for biospecimen number*	*Biobank credit in publications*	*Deposit or make data publicly available*	*Lodge manuscripts with biobank*	*Reporting to biobank*	*Return unused samples*
1	Australasian Biospecimen Network (Australia)	External recommended	None specified	Recommended	Acknowledgment recommended	Recommended; return clinically relevant data	Recommended	Recommended at project completion	Recommended
2	Australian Prostate Cancer BioResource	Internal	Are or collaborate with an Australian researcher	Required	Authorship	Required	Required	Annual	Required
3	BancoADN (Spain)	External	Are or collaborate with a Spanish researcher	Required	Acknowledgment	Required	Required	Within 2 years of specimen receipt	No
4	Canadian Tumor Repository Network	Internal	None specified	Varies	None specified	Recommended	Recommended	Varies	No
5	Centro National de Investigationes Oncologicas Tumor Bank Network (Spain)	Internal/external not specified	Are or collaborate with a Spanish researcher	Required	Acknowledgment	Varies	Varies	Varies	Required
6	Chernobyl Thyroid Tissue Bank (Russian Federation)	External	None specified	Required	None specified	Return clinically relevant data	Varies	Within 3 months of study completion	Required
7	Confederation of Cancer Biobanks (UK)	Internal/external not specified	Not recommended	Recommended	Acknowledgment recommended	Recommended	Recommended	Regular reporting recommended	No
8	Cooperative Human Tissue Network (USA)	Internal	None specified	Varies	Acknowledgment	Varies	Varies	Varies	No
9	EuroBioBank	Varies by participating bank							
10	Kathleen Cuningham Consortium for Research into Familial Breast Cancer (kConfab; Australia)	Internal	None specified	Required	Authorship	Required	Required	Annual	Required
11	onCore UK	Not yet distributing biospecimens							
12	Singapore Tissue Network	Internal	None specified	Required	Acknowledgment	Varies	Required	Varies	No
13	Tubafrost: European Human Tumor Frozen Tissue Bank	Internal	None specified	Required	Acknowledgment	Varies	Required	Varies	Required
14	UK Biobank	Not yet distributing biospecimens							
15	Victorian Cancer Research Tissue Bank (Australia)	Internal	None specified	Varies	Acknowledgment	Return clinically relevant data	Required	Annual	No
16	Wales Cancer Bank	External	None specified	Required	Acknowledgment	Varies	Varies	Varies	No

Note: EuroBioBank-access policies vary by participating bank, while onCore UK and UK Biobank-access policies are not yet distributing biospecimens.

that have been collected for broad research purposes. The consortium is nonprofit and is funded with government and charitable contributions. It offers tissue, blood, purified nucleic acids, or tissue microarrays, and anticipates the return of any clinically relevant data. The cost-recovery fees for nonprofit entities range from US$18 per tissue section to US$139 per paraffin block; a different fee scale is in place for commercial entities.

United Kingdom

The *Confederation of Cancer Biobanks*[5] is a nonprofit collaboration between several UK cancer repositories to form a single, virtual biobank of tissue, blood, and purified nucleic acids. Each participating repository has its own funding sources with cost-recovery and fee-for-service mechanisms. It is recommended that research data be made publicly available.

The nonprofit *Chernobyl Thyroid Tissue* Bank,[6] with its coordinating center located in the United Kingdom, collects, stores, and offers researchers broad-use biospecimens from thyroid cancer patients in Russia and Ukraine who were exposed to fallout from the Chernobyl nuclear reactor accident. Researchers are not charged for the tissue, blood, nucleic acids, and tissue microarrays, but may be charged for shipping or for additional effort on the part of the Eastern European Institute. Clinically relevant data and any unused samples are to be returned to the bank. This initiative is funded by the European Commission and the governments of the United States and Japan.

onCore UK[7] is a centralized cancer biobank offering tissue, blood, and purified nucleic acids that have been collected for broad research purposes. It is a nonprofit entity funded by the British government, public/advocacy groups, and cost-recovery fees assessed to researchers. In early 2009 onCore UK decided to change its focus from that of a biobank actively collecting tissues to exclusively "focus on the promotion of biobanking and its associated activities within the research community and the health service." onCoreUK's 4-year experience in attempting to create a nationalized standard approach to tissue collection led its management to the conclusion that the "needs for biobanking can be effectively fulfilled by local biobank activity."

The *UK Biobank*[8] is a population-based initiative that banks blood and urine from British participants for broad research purposes. It is a nonprofit endeavor jointly funded by the UK government and charitable organizations. When the biospecimens become available to investigators, a cost-recovery plan will be in place to defray the costs of obtaining the samples and accompanying data as well as any preparation or analysis requirements requested by the accessing researchers.

The *Wales Cancer Bank*[9] is a nonprofit federation of repositories in Wales that bank cancer biospecimens collected for broad research purposes. It receives both government and charitable funds. The banked tissue and blood biospecimens will be offered according to a cost-recovery system that will vary depending on the sample type and what processing the samples have undergone.

Continental Europe

The *BancoADN*[10] is a nonprofit organization funded through Spanish federal and regional governments and the University of Salamanca. It collects and stores blood, DNA, and cells for broad research uses; these are available to Spanish researchers and their collaborators. Although it is a not-for-profit endeavor, its cost-recovery methods include having the sample-request team cover handling, maintenance, and transportation in addition or payment of €1 per microgram of DNA for nonprofit research organizations (€1.54 per microgram is charged to for-profit entities). Researchers are expected to "provide detailed information of the analyzed parameters in the collection of samples."

The *Centro National de Investigationes Oncologicas Tumour Bank Network*[11] comprises a federation of Spanish repositories of cancer tissues collected for broad research purposes and available to Spanish researchers and their collaborators. It is not-for-profit and is funded by donations from commercial and private entities. Researchers may access the biospecimens for €15, which helps defray handling and transportation costs; nonstandard procedures may be requested, although the full cost of these is borne by the researcher. Unused samples are expected to be returned to the bank.

EuroBioBank[12] is a nonprofit federation of repositories for rare-disease DNA, cells, and tissue, which have been collected for broad research purposes. While the network is funded by the European Commission, charities and the governments of each member country fund the member biobanks. Each member bank has its own cost-recovery policy; biospecimens are not sold for profit but processing and shipping fees may apply.

Tubafrost[13] is a nonprofit federation of cancer biobanks across Europe funded by the European Commission. Participating repositories offer tissue biospecimens collected for broad research purposes, and anticipate return of any unused samples. Investigators interested in accessing biospecimens negotiate cost with each source biobank.

North America

The *Canadian Tumour Repository Network*[14] (CTRNet) is a nonprofit consortium of biobanks funded by the Canadian government. Each participating biobank may store cancer patients' tissue, blood, and saliva biospecimens, which are collected for broad research purposes. It is recommended that researchers make data publicly available. CTRNet is currently developing a partial cost-recovery fee structure for biospecimen access.

The *Cooperative Human Tissue Network*[15] (CHTN) is a nonprofit federated organization funded by the US National Cancer Institute. For a nominal processing fee and the price of shipping, it offers tissue, blood, and tissue microarrays available from existing collections or collected prospectively from cancer patients for specific research projects.

Other than the CHTN, the US Government to date has not supported a comprehensive national biobanking program. Biorepositories in the United States tend to be localized in pathology laboratories, or supported as centralized resources within academic and clinical institutions.[16] Some small disease-specific networks have been developed. However, due to the difficulties that academic and industry programs have in obtaining adequate numbers of high-quality specimens for research, the NCI is developing a new national biobanking program, caHUB, for cancer Human Biobank. caHUB (see description at http://biospecimens.cancer.gov/cahub/

default.asp) is being planned initially as an NCI-supported program that will become a public–private partnership over time. As caHUB is under development, much can be learned from the issues already faced by the programs highlighted in this review, especially in terms of governance and business models.

Asia

The *Singapore Tissue Network*[17] is a disease-based operation that prospectively collects and banks tissue, blood, cell, and DNA biospecimens from Singaporean cancer patients. It is not-for-profit, receiving funding from the Singapore government's Biomedical Research Council.

Discussion

The biobanks and networks reviewed in this article operate under a variety of economic and governance models, and although generally successful, some challenges are worth noting to inform new initiatives.

Issues of tissue access and custodianship are often serious challenges to the long-term sustainability of a biobank. For disease-based biobanks, much depends on the location of the biobank in relation to the diagnostic workflow. For example, biobanks can readily be established in hospital pathology departments, because the needs of diagnosis dictate that samples flow through these departments; it is the best practice that the pathologist must examine resected specimens first and take samples for diagnosis, before samples may be obtained for research. However, the establishment of a centralized collection, remote from the biospecimen procurement site, presents a more difficult problem. For such a centralized collection to be successful, clear incentives must be in place, for example, financial reimbursement, to encourage those responsible for the local hospital procurement to provide their samples to a central biobank, otherwise the work of specimen collection and annotation simply distracts hospital staff from their primary clinical and/or research responsibilities.

Financial support is one incentive to encourage contribution of biospecimens to a centralized disease-based biobank. This may include payment for staff salaries and equipment at the local collection site, which may retain some portion of the samples for local research use. Biobanking is an expensive activity requiring dedicated staff to obtain patients' consent and collect samples; the success of this incentive depends on the level of funding available. Experience has shown that the costs of establishing and maintaining a biobank or biobanking system are often not well understood at the beginning of a project. The incentive used in project-driven collections is generally research collaboration, whereby clinician–investigators at the local procurement site are actively involved in research projects using the large sample collections at the central biobank. This approach has recently been adopted by the Singapore Tissue Network, after several years of general collection.

The federated network model (see Table 1 for examples) provides a popular alternative to the centralized biobank model. In a federated network, staff members at the collection site are the custodians of the samples they collect. Membership in a federated network includes the condition that some portion of the local collection is made available to researchers at other sites. Incentives for membership in the network may include financial support and the advantage of access to collections at other sites. This model requires that perceived "ownership" rights to specimen collections are overcome for the benefit of the network.

A national biobank, for example UK Biobank, that obtains public funding requires public support, and needs to have strong leadership that is engaged in assuring the public that specimens are being collected for the common good and are being used in an ethical manner for productive scientific endeavors. In general, public confidence is ensured by the existence of ethics committees or institutional review boards that monitor sample collection and use, together with privacy laws that protect the confidentiality of patients and donors.

The biobanks outlined in this review, although they operate under a variety of models, share many of the following characteristics, which in most cases are detailed in their Web sites:

- Governance models with clearly stated technical standards, ethical guidelines, access policies and procedures, scientific rationale, and long-term custodianship plans, that is, assuring that the program is sustainable from technical and economic perspectives.
- A strong quality assurance/quality control program with clearly defined standard operating procedures, and regular audits to assure compliance.
- A comprehensive business model that, unless it is entirely supported by public funds, has a sustainable cost-recovery plan or other means to assure consistent long-term financial support.
- In general, adherence to a set of best practices governing both technical and ethical/legal issues, such as those published by the International Society for Biological and Environmental Repositories (ISBER, http://www.isber.org) and NCI (http://biospecimens.cancer.gov).

As the biobanks and networks described here mature and others are established, the factors that contribute to their success will become clearer. Regular communication between biobanks helps administrators identify these success factors and stay abreast of technical advances and policy changes in the field. ISBER provides a forum for such communication through annual meetings, working groups, and listserv discussions. Recently, in recognition of the increasingly international nature of biospecimen resources, ISBER created an Asian chapter; additional international chapters are under consideration. The Public Population Project in Genomics[18] (P3G) provides another forum, with special emphasis on population biobanking. P3G maintains an extensive set of Internet reference materials (the "Observatory") of international biobanking guidelines and other materials that facilitate international coordination and collaboration.

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