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GOVERNANCE MECHANISMS AND POPULATION BIOBANKS : BUILDING A FRAMEWORK FOR TRUST

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Biobanks have become increasingly important for the study of health and disease. Population biobanks are resources for the study of common diseases. They link genetic data with information on health status, lifestyle and environmental factors. Public trust is vital to these biobanks, as they depend on the altruistic participation of individuals. To secure this trust and good will, population biobanks have put in place various governance mechanisms, for example, independent oversight committees and data access committees. In some countries, specific legislation has been enacted, while others rely on guidelines and existing general health, safety and data protection legislation. This article examines the importance of public legitimisation, why governance is important in the context of biobanks, and the governance mechanisms that biobanks currently use.

Biobanks, collections of biological materials and their associated data,[1] have for many years provided a resource for the study of health and disease. The nature of biobanks and their specific aims vary, but their number is increasing steadily. Large scale (>10,000 samples) population biobanking projects are a more recent phenomenon. These biobanks will be resources for research into common diseases by linking genetic data with information on health status, lifestyle and environmental factors.

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A population biobank has been defined by the Council of Europe as:

> a collection of biological materials that has the following characteristics:
>
> i. the collection has a population basis;
> ii. it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects;
> iii. it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated;
> iv. it receives and supplies materials in an organised manner.[2]

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A number of large scale longitudinal population biobanks or 'resources' are now in existence and are collecting data and samples from donors (e.g. CARTaGENE[3] and UK Biobank[4]).

How and by whom these resources will be governed are vital issues when considering their scientific objectives. Governance has been defined as:

> The process of policy orientation and management that guides and regulates research under ethical and scientific norms so that the results can be used for the benefit and improvement of the health of the population.[5]

Governance frameworks have further been described as "…the agreements, procedures, conventions or policies that define who gets power, how decisions are taken and how accountability is rendered".[6] Kent has written that governance frameworks for population biobanks, "exist at the intersection of legislation…codes of practice…and public legitimisation".[7] This paper seeks to first examine the processes by which population biobanks solicit and secure public legitimisation for their projects; second, look at why governance is important in the context of biobanking; and third, present an international overview of the variety of governance mechanisms and normative frameworks that are currently being used by biobanks, with an overall goal of providing guidance for the future.

1. Public Legitimisation

To succeed, population biobanks require, amongst other factors, the support of their target population and the population at-large. Public trust is important to the successful creation, running and financing of a biobank.[8] People are interested in how public money designated for these projects is being spent. They want to know how the science is being conducted and under what conditions, whether the use of that science is acceptable to them, and what impacts the results of the research might have for them, their families and friends, and society in general.[9] If the public approves of the research, pressure can be placed on governments to fund these activities. Researchers will then begin to produce results, enabling them to return to funders for additional money to continue their work. If the work has been shown to be progressing positively and the public approves of the path it is taking, funders will be able to continue to support the work, and the cycle continues. If there is a breakdown, where the research is not beneficial, it is conducted in an unethical manner, or the government changes priorities against the public's will, the cycle can be broken and arguably the public's trust will have been betrayed. If such a betrayal occurs, government and researchers may find it more difficult to engage the public in future activities.

More specifically, there must be individuals willing to participate in the biobank – without people willing to donate their biological samples and provide their health and related data over time, population biobanks cannot build the necessary infrastructure for future disease studies.[10] However, recruitment into population biobanks is inherently different from participation in other research, such as clinical trials. Population biobanks seek to involve people in a different form of medical research. First, as opposed to traditional clinical investigations involving patients with specific diseases, participants in a population biobank are disinterested citizens. As these resources are long-term and follow participants over time, it will be many years before the studies using these resources will provide results. There is no expectation that participants will benefit personally or receive individual results, although they may feel they have created a benefit for future generations. Second, and again in contrast with clinical investigations, researchers creating biobanks cannot always inform potential participants of the specific research purposes for which their samples and data will be used. Therefore, participants must show their trust in the biobank by giving a broad consent to unspecified future uses within a governance framework. Third, participants trust that the biobank will protect their personal information, whether that is questionnaire data about their lifestyle, their medical history or the genetic data contained in their blood or urine sample. Biobanks must protect these materials from unauthorised use and maintain the confidentiality of

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participants over long periods of time. Participation in a population biobank is an altruistic act and, because of the reasons given, "…creates a requirement to create an ethical framework that values and protects the contribution of the individual".[11]

In order for people to wish to participate, they must trust that the population biobank is worthy of their support. But how does one go about securing individual and public trust? Methods vary and most population studies go through extensive public engagement activities prior to receiving funding. Public legitimisation can come in many forms. In the initial stages of a population resource project, planning documents, budget projections and decision-making processes are made available for public viewing and comment. Biobank planners often will then conduct public consultations introducing the aims, plans, and anticipated outcomes of the population biobank and encourage comment and discussion.[12] In addition, population biobanks will in most cases be required to undergo independent ethics and scientific review before they can receive the necessary funds to begin work. These initial consultations and reviews aid planners in designing the appropriate governance structures needed to ensure ongoing oversight of the biobank.

2. Governance and its importance for biobanks

One important and vital avenue for biobanks to maintain and honour public trust is through the creation and use of governance mechanisms within broader frameworks. Governance allows people and institutions to act by constraining behaviour within an agreed social framework. Such frameworks reflect the society in which they are situated and may consist of laws, social norms, ethical codes, etc. Governance is exercised within specific contexts so that, "…traditional freedoms may be enjoyed, commerce may occur, the arts and culture may flourish".[13] Context is important; governance frameworks must be adjusted to meet the needs of those acting within specific spheres.

As in other areas of research, population biobanks have put governance mechanisms into place within frameworks to ensure the proper running and accountability of their work. These frameworks serve to ensure that the biobank is acting within its remit, as well as within the applicable laws and regulations of the particular society in which it is located. Beyond the need to act within the law, population biobanks raise specific legal and ethical issues and their governance frameworks must take these into account.

There are risks if such frameworks are not put into place. In the past, biomedical and genomics research and practices have lost public trust. Two examples at the international level are: (1) the rejection in Europe and elsewhere of genetically modified (GM) crops and products due in part to poor communication around the science and lack of attention to public concerns;[14] and (2) the loss of public trust in tissue and organ donation following the scandals surrounding the retention of tissue and organs without consent in England.[15] For each of these situations, the context (i.e. the time, place, circumstances) in which they took place must be taken into account. There are now indications that the public has renewed its support for tissue donation.[16] In the case of GM crops, at that time Europeans may not have seen a need for them, as the economy was strong and lack of food was not an issue. Opinions may change in the future, with the rise in food and fuel costs.

Losing public support can seriously damage a field of research. Moreover, regulatory responses to such situations may later be seen as excessive. For example, in response to the organ retention scandal in the United Kingdom, additional legislation was created.[17] It aims to protect the public but some claim that it may have had the opposite effect of hindering research that could benefit the public.[18] Without a clear governance framework, population biobanks may err by adding multiple layers of oversight, mistakenly believing these will enhance public trust when they may simply limit the ability to conduct research in the public interest as a result of added bureaucracy.

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3. Existing mechanisms and frameworks that impact biobanks

Currently, three areas of 'normativity' influence the governance of biobanks: international guidelines, laws specific to biobanks and other general related practices.

A. International Guidelines

While there are no harmonised regulations for biobanks that are binding on the international community, international organisations have created guidelines specific to the biobank community. A closer look at what these organisations have suggested in the past can help chart how perspectives have changed and reveal how trends may evolve in the future.[19] As the Human Genome Project progressed in the 1990's, the Human Genome Organization (HUGO) prepared a *Statement on the Principled Conduct of Genetic Research* (1996),[20] followed by a *Statement on DNA Sampling: Control and Access* in 1998.[21] The latter, while focusing on samples, was primarily concerned with individuals and families. In contrast, the more specific 2002 *Statement on Human Genomic Databases* specifically addresses the 'public' nature of such large-scale studies. It recommends that primary data be recognised as "global public goods" and that "[a]ll humans should share in and have access to the benefits of databases".[22] In addition, the 2002 *Statement* recommends that respect should be given to the choices made by individuals, families and communities involved with databases and that "[m]echanisms should be established to ensure respect for such choices".[23]

In 1991, the Council of International Organizations of Medical Sciences (CIOMS) published *International Guidelines for Ethical Review of Epidemiological Studies*.[24] This document proposed guidelines for the proper conduct of epidemiological studies within different populations and set ethical standards for conducting research with specific communities, groups, and populations, taking into account their values and culture. These guidelines have recently been updated; the *International Ethical Guidelines for Epidemiological Studies* (2008)[25] now place greater emphasis on genetics and epidemiological research, fields that will only expand with greater access to large scale population resources. Without implicitly addressing the concept of governance, this latter report does refer to the review of large scale epidemiologic research in the section addressing guidelines for ethical review committees:

> In a large multi-centre epidemiological study… such a trial usually has a set of committees which operate under the direction of a steering committee and are responsible for such functions and decisions. The function of the ethical review committee in such cases is to review the relevant plans with the aim of avoiding abuses.[26]

The International Bioethics Committee (IBC) of UNESCO has prepared principles geared toward the protection of persons and populations involved in genetics research. In 1997, UNESCO adopted the *Universal Declaration on the Human Genome and Human Rights*.[27] This *Declaration* does not provide any concrete direction on governance, although it does reinforce the responsibility of every government or political power:

> States should take appropriate steps to provide the framework for the free exercise of research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes.[28]

In 2003, the IBC also produced the *International Declaration on Human Genetic Data* that specifically mentions in Article 6(b) that:

> Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.[29]

It is interesting that article 6(b) sets some guidance for the role of institutional ethics

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committees when there is a national or other governance committee in place. The *Declaration* states that "[i]t is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures."[30] It goes on further to recommend that:

> States may consider establishing a framework for the monitoring and management of human genetic data, human proteomic data and biological samples based on the principles of independence, multidisciplinarity, pluralism and transparency as well as the principles set out in this Declaration. This framework could also deal with the nature and purpose of the storage of these data.[31]

General codes of ethics for research involving humans are also important for biobanks. Of particular note is the 2004 *Declaration of Helsinki* which governs research involving human subjects as well as identifiable material and data.[32] Furthermore, in 1997 the Council of Europe in the *Convention on Human Rights and Biomedicine* maintained the need for "multidisciplinary review of ethical acceptability".[33] The 2005 *Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research* goes into greater depth regarding ethical review.[34] In a section relating to ethics committees, it states that every research protocol needs to be submitted and approved by a research ethics committee. However, there are no specific references to large scale population genetic research projects and their governance mechanisms as this Additional Protocol was not intended to cover collections of biological materials which would be stored for future research.[35]

More recently, the Organisation for Economic Co-operation and Development (OECD) created its *Best Practice Guidelines for Biological Resources Centres*[36] and is currently preparing a draft set of guidelines on human biobanks and genetic research databases (HBGRDs).[37] The former is designed to give recommendations on the maintenance of a biological resource centre (BRC) for the storage of biological samples. It sets the criteria that need to be followed in order to maintain good quality samples and to be able to share them across borders. Such BRCs can store sample collections from many projects that do not have the same objectives. A good example is the UK DNA Banking Network.[38] The new 2008 draft guidelines on HBGRDs have a specific section on governance entitled *Governance, Management, and Oversight*. Without specifically mentioning the need for an independent governance committee or legislation on biobanks, the section addresses several major aspects of governance, including stating that, "[t]he governance structure should ensure that the rights and well-being of the participant prevail over the research interests of the initiators and users of the HBGRD".[39]

B. Legislation

In some countries, legislation has been enacted specifically for biobanks. We will discuss several countries that have adopted biobank-specific legislation: Estonia, Norway, Sweden, and Latvia, as well as France and Spain, which have incorporated 'biobank' provisions in their legislative structures. An examination of these laws shows how legislation can vary from the quite specific to the more general in regards to regulating biobanking activities.

Estonia established the *Human Genes Research Act* in 2000.[40] This Act was specifically designed to govern the establishment of a national biobank by the Estonian Genome Project Foundation. It governs genetic research conducted with the 'Gene Bank' and mandates requirements for the maintenance of the biobank as well as for a Data Protection Commissioner and a Supervisory Board to oversee the biobank.

In Norway, the *Act Relating to Biobanks* (2003) also covers the collection, transfer, processing and organisation of materials and data in a biobank.[41] However, this *Act* places less emphasis on the collection of samples for genetic research, using broader terms such as 'research purposes' as opposed to specifically focusing on genetic research. The Norwegian *Act* differs from the Estonian *Act* on the subject of governance mechanisms. In Norway, the decision to create an oversight body to

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govern a biobank is taken by the Ministry and depends on various factors; for example, the ability to link samples to the donor.

Sweden adopted the *Biobanks in Medical Care Act* (2003) to control the organisation and use of biobanks.[42] This *Act* contains a section on 'supervision'. It recognizes the role of the National Board of Health and Welfare to ensure that every biobank complies with the *Act*. It states that the supervisory authority should be allowed to access any document or areas needed. However, it draws a line between data and samples by stating: "[t]he supervising authority pursuant to the *Personal Data Act* (1998:204) shall supervise the processing of personal details".[43] The Swedish legislation is different from the others because it is specific in terms of its application. For example, some parts of the *Act* apply to tissue samples taken for transplantation and Chapter 5 is dedicated to the Swedish PKU registry. Although specific, it lacks specificity on governance. This might be explained by the fact that the *Act* concerns collections of samples coming from medical care as opposed to the creation of a large, population resource, such as is the case with the Estonian *Act*.

In 2003, Latvia also adopted a biobank-specific law, the *Human Genome Research Law*. Similar to the Estonia law, the purpose of this law is to regulate the establishment and operation of a national genome database for the State population. The last chapter of the law describes the governance mechanism for the genome database. Like Estonia, the State Data Inspector is responsible for oversight of the resource and for receiving complaints. The Central Ethics Committee also has a governance role: "[t]he Central Ethics Committee shall evaluate the compliance with the principles of ethics in genetic research and establishment and operation of the genome database".[44]

In 2007, Spain adopted *Law 14/2007, of 3 July, on Biomedical Research*. As indicated by the title, this law covers biomedical research generally, but it also has a specific chapter on biobanking. Title I contains general provisions about the object and scope of the law, definitions and the role of research ethics committees. However, it does not clearly state that an institutional research ethics committee should play a role in biobank governance. Rather, it should "watch over the compliance of the procedures that permit to assure the traceability of samples of human origin, notwithstanding that provided in the legislation on the protection of data of a personal nature".[45] Tittle 5, Chapter 4, on biobanks relates to the requirements institutions must follow in setting up biobanks. Yet, this law is also vague on the specific governance mechanisms needed to regulate biobanks. Again, this may be due to its broad nature, covering both medical care and research samples. Spain's law does describe the creation of the Spanish Committee on Bioethics. This body advises on the ethical and social implications of biomedicine and the health sciences, but was not mandated to govern biobanks. It also mentions that a biobank "shall have a scientific director, a person responsible for the files and shall be assigned two external committees, a science and an ethics, respectively".[46] Any Spanish biobank must be registered in that country's national registry of biobanks.[47,48,49]

Although France has not adopted a specific law regulating biobanks, specific articles pertaining to the collection of data and samples for genetic research have been incorporated into its *Code de la santé publique*. Samples collected during medical care can be used for research if patients are notified and do not object.[50] When a data and sample collection is created for the sole purpose of research, The Agence française de sécurité sanitaire des produits de santé must be notified.[51] This requirement is also included in the articles pertaining to the donation and use of data and samples for research purposes.[52] In the case of donation, the Ministry in charge of research or, if applicable, the Regional Hospitalization Agency also needs to be advised. Little additional detail is given regarding the governance of such resources, except that the authority in charge of oversight needs to be an agency approved by the Ministry in charge of research.[53]

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Regardless of the differing scope of these national biobank-related laws, they all cover the organisation of biobanks and regulate access, transfer and use of samples and related data. Some laws are more detailed on certain aspects than others. For example, the Spanish law has a section on traceability and limited use of genetic analysis. The Estonian *Act* is more detailed on the composition of the supervisory board and on data protection. The Norwegian *Act* discusses the possibility of transferring a biobank or a part of biobank to another country. Except for Estonia, all countries discussed have provisions in their legislation regarding the closure of a biobank.

There is no consensus as to whether specific biobank-related legislation is beneficial or a detriment to scientific research in this area. Is it therefore possible to determine whether it is more efficient for a country to have specific biobank legislation or to rely on other governance mechanisms found in biomedical research guidelines or laws generally?

C. Other general related practices

This section covers a wide array of diverse forms of guidance and normative activities. Together, they form a large body of components that biobanks can use when creating a governance framework. Most countries use such common infrastructure elements to create a larger framework to guide biobanking activities. These common elements include: applicable legislation, regulations and standards; scientific and ethics evaluation; and professional and institutional guidelines.

All biobanks must adhere to the legislation and regulations already extant in their jurisdiction. Applicable legislation, and associated regulations and standards, can include those dealing with human rights; data protection; health and safety; statistics; use of human tissue, blood and other biomaterials; and the protection of humans involved in research.[54] Scientific and ethics research review, legislated in some countries but guided by professional regulation in others, seeks to ensure, amongst other concerns, that research is necessary, has scientific merit, is an appropriate and potentially beneficial use of funds, that the researchers that wish to conduct it are qualified and capable, and that the research has been designed and will be carried out in an ethical manner. These forms of review are usually carried out by institutional committees representing funders, the sites where research will be carried out, or by governmental bodies.

In addition to these mechanisms, resources often create additional committees for another level of review. The UK Biobank is the most obvious example. It has an Ethics and Governance Council (EGC), tasked as the 'guardian' of the biobank's Ethics and Governance Framework.[55] The EGC monitors UK Biobank's conformity with the Framework and advises generally on ethics and governance issues. It was created in response to public consultation – an example of a biobank taking action to secure public legitimisation, as discussed earlier.[56] In contrast, other biobanks have chosen not to have such a committee, as existing laws and internal and institutional mechanisms are seen as sufficient to secure the credibility and ethical workings of the biobank. Biobanks often use multiple committees in their work. For example, sample and data access committees review the requests of researchers and seek to ensure that the data and materials are used for scientifically valid and ethical research. Likewise, scientific advisory committees are used by biobanks to help determine scientific goals and how they can be reached.

Finally, professional and institutional guidelines cover a wide range of topics. Many international and national organisations have written guidelines with examples of and recommendations for good practice. A comparison of many of these has been conducted at the Public Population Project in Genomics (P^3G) and made available online.[57] Such a comparative table can help biobanks find the information that will be of most help to them. From these examples, biobanks can then craft their own guidelines to reflect their cultural context. For example, the principle of informed consent is an internationally acknowledged requirement for ethical conduct of research. Informed consent

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procedures notify donors that they are able to withdraw their participation from a biobank at any time, as well as of the confidentiality measures put in place, amongst other information. However, as with biobanks, consent mechanisms necessarily vary depending on the circumstances. The researchers involved with the International HapMap Project found that consent procedures varied widely for the four populations invited to participate in the project, due to "vastly different community structures and cultural norms".[58] The purpose of the HapMap was research on genetic variation with the deposit of all samples in the Coriell Institute for Medical Research.[59] The researchers considered that, in order to secure public support and participation, they needed to structure their interventions to meet the requirements of the participating population.

4. Conclusion

There may be several benefits to having biobank specific legislation.[60] It can provide participants rights and protections specific to the biobanking context. For example, participants in the Estonian Genome Project can be assured that their personal information and samples will not be made available to law enforcement agencies because the legislation specifically prohibits it. In contrast, participants in UK Biobank can only be assured that the resource will strenuously resist such access. However, the absence of a specific biobank law does not mean the absence of governing legislation. Even with specific legislation, other existing laws also apply, for example, human rights and data protection legislation.

Specific biobank-related legislation may prove too inflexible to react to natural changes in science, law and the culture in which the biobank is operating. A possible alternative regulatory mechanism could be to mimic the way in which the United Kingdom has moved to regulate *in vitro* fertilisation. The UK Parliament laid down, in general terms, what it wished to achieve in the *Human Fertilisation and Embryology Act 1990*.[61] The UK Human Fertilisation and Embryology Authority (HFEA),[62] a statutory body, was created as part of the *Act*, to turn the *Act*'s intentions into a workable code of practice. In the context of biobanks, legislation could be written laying out, for example, the perceived importance of these resources to a country, how they could further scientific research, and the ethical principles that they should follow. In turn, a statutory body could then create a regulatory structure that would implement the legislation, while allowing it enough flexibility to react to the changing nature of this area of scientific research, as well as to the needs of society. Finally, the range of tissues used in biobanks and other disease studies is potentially unlimited and can include tissues left over from medical care, from archived collections or from deceased persons. Perhaps consideration should be given to a general framework law on human tissues together with the regulatory yet flexible model borrowed from the HFEA. Could this serve to "de-stigmatize" the use of tissues for genetic research?

As we have shown, biobanks use many different and context-specific mechanisms to create frameworks to govern their operation. However, in what form, when, and in what combination, are these various mechanisms needed to best secure public trust in a population biobank? Is one framework appropriate for all biobanks? Should every country enact biobank-specific legislation? Should every biobank have a proscribed set of oversight committees? Is there a 'one-size-fits-all' framework that biobanks should use? We would argue not. Context must drive the creation of governance frameworks. Biobanks naturally reflect the populations that make up their resource. As all biobanks differ, so does their need to adhere, or adapt, to differing legislative, social or normative approaches.

This is not to say there are no opportunities to guide those setting up or managing biobanks to ensure that they have reliable and efficient governance frameworks in place that will enhance their ability to conduct research, as well as engage the public and create an impetus to participate. We suggest that, based on their particular circumstances, population resources should set up governance mechanisms to provide oversight to ensure the following:

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Scientific Aspects

- The research conducted will advance science and benefit the population and individuals in the future.
- The resource's procedures and activities will receive regular independent scientific review.

Ethical Aspects

- The confidentiality of personal information will be protected.
- The resource's procedures and activities will receive regular independent ethics review.
- All requests for access to data and samples will be reviewed.
- The resource will comply with all relevant legislation, guidelines and standards.

Expertise

- There will be expert representation on all governance and oversight committees as appropriate (i.e., epidemiologists, bioinformaticians, sociologists, geneticists, etc.)

Communication Aspects

- The population will be kept generally informed of the research conducted using their data and samples.
- Participants will be able to register their comments, queries and complaints to the resource, with the assurance that any complaints will be addressed.

With these and other safeguards in place, in whatever form they might take, the resource will make great strides toward engendering the trust and encouraging the participation of the public. In addition, further work is necessary to place these general principles within more specific governance mechanisms that can then be considered by biobanks and used, if appropriate, depending on their circumstances. The Ethics and Policymaking Core of the Université de Montréal is currently researching and creating model governance frameworks for the use of the population resource community.

We believe that resources must not assume that instituting governance frameworks is only necessary because of the nature of these genomics resources. What is to be avoided at all costs is a repeat of the genetic exceptionalism of the 1990s. If most of these population resources wish to study normal genome variation in a given environment over time, then ethical and legal norms should not treat the data and samples as 'special,' thereby repeating genetic exceptionalism, this time at the level of whole populations.

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