Biobanks hold bio-objects for use in research or clinical settings. They provide tissue with mechanisms of storage and distribution and an institutional framework of reference that gives value and status to the tissue held. As such, they are exemplar sites of bio-objectification.

UNDERSTANDING BIOBANKS AND THEIR BIO-OBJECTS: GOVERNANCE CHALLENGES EXPLORED

BACKGROUND

Biobanks are collections of biological materials, such as blood or tumour samples, and associated data. Biological materials and data have been used in biomedical research practices for a long time. Yet, the debates that have accompanied the emergence of biobanks over the past two decades demonstrate that once materials and data are assembled in biobanks, their meaning changes and is destabilized. That’s why biobanks are sites of bio-objectification and bio-identification processes. Formal guidelines and informal practices work to bring stability to the form, supply, and documentary practices of the Bio-objects biobanks hold. However, biobanks are also a widely diverse group of organisations. They vary in the tissue they hold (stem cells, seeds, whole mice, urine), their scale (from international infrastructures to near-personal collections) and their purposes.

CURRENT UNDERSTANDING

During the past decade the number of biobanks that have been set up has increased tremendously. This is due to the relevance that large collections of tissue and data are believed to have in the way disease can be studied, as well as the treatments and cures that may follow. In setting up and formalizing networks of acquisition, storage and exchange, however, biobanking also gives rise to ways of governing and acting upon human individuals and entire populations, both in the ways diagnosis and treatment are developed for individuals, but also in the ways public health is seen and managed. While detailed analysis and assessments of biobanks exist the ongoing fluidity of social, legal and technical contexts requires continued focus on the governance challenge posed.

FUTURE TARGETS FOR POLICY

The unfolding governance challenges are many, and future challenges approaching the horizon include:

- A focus on understanding the ways in which biobanking practices give rise to new forms of governance in relation to healthcare management and delivery.

- A critical examination of the implications that existing collections may have in relation to other biomedical research fields, such as induced pluripotent stem cell research.

- A better understanding of the ways in which entire populations are brought into global systems of tissue and information exchange and flows.

- Concern with the potential oversupply and fragmentary provision of biobanking institutions.

KEY CHALLENGES IN CURRENT GOVERNANCE INSTRUMENTS INCLUDE

1. Fostering the uptake of Responsible Research and Innovation (see page four for elaboration).
2. Understanding that biobanks are not just governed from above, as things that are governed, but rather that biobanking practices also give rise to forms of governance that can extend beyond conventional mechanisms of informed consent. They transform the ways in which biomedical research is conducted, and health care is delivered.
3. Embracing a full life-cycle approach to planning biobanking activities that takes seriously the implications of funding cycles to include flexibility for the unanticipated and foregrounds the ethical and practical issues involved in biobank merger and biobank closure.
4. Supporting better understandings of non-western consent mechanisms including verbal or community consent, ‘lay’ consent and assumed assent, and exploring adaptive governance mechanisms that go beyond consent procedures to involve donors in biobank decision making.
Novel biological materials become both recognizable and valuable through the twin processes of bio-objectification and bio-identification. Subsequent to these processes we encounter stabilised bio-objects that obtain the qualities of being knowable, recognisable, and transferable. In all three stages biobanks are faced with distinct regulatory challenges, the character of which results from the status of the novel biological tissue across the bio-objectification, bio-identification and stabilized bio-object continuum. We explore each below:

### 1. BIO-OBJECTIFICATION (i.e. the ranges of experimental work which is devoted to the exploration and fashioning of new ‘bio’, new forms of life).

- Tissue and data contained within biobanks can emerge from unconventional (secondary use) sources (e.g. dried blood spots from neo-natal screening) with prospective value as research resources. This changes the status of the samples from something well known (for instance, a part of a clinical record) to something less defined. It also disentangles the sample from a well-defined context, such as a context of clinical care or a national screening program, and relocates it in a network of more uncertain activities and practices. This process destabilizes the traditional distinction between research and care.

- Biobanks operate within a complex web of national and international cultures. Their operation – and thus the mechanisms of bio-objectification they engage in - can be framed by local values.

- During processes of Bio-objectification the future use of novel tissues (e.g. new forms of embryos for stem cell derivation) remain uncertain, and these uncertainties convert into banking uncertainties over what mechanisms of storage and ethical oversight are appropriate.

### 2. BIO-IDENTIFICATION (i.e. the social labour that is undertaken to ensure the (co-)relative identity of bio-objects to other forms of life is made clear, especially in regard to say IP or regulation, such as the definition of a ‘pre embryo’ etc).

- Governance mechanisms can facilitate the transformation of residual / secondary use biological material into a biobank thereby enabling circulation and possible commercialization of prospective research resources.

- Processes of bio-identification associate with a plurality of accounts of the moral, epistemological and ontological status of the tissue concerned, facilitating diverse ranges of stakeholder opinions and necessitating strategies for appropriately deeming some viewpoints more salient than others.

- The social labour inherent in bio-identification is diverse and spread across multiple people with multiple roles. The process of establishing effective governance structures can frequently render some sites of social labour less visible (donors, laboratory technicians, dissenting voices) while elevating and imposing others (governmental bodies, prominent spokes people, selectively appointed representatives of broader and lay opinion).

- Novel approaches undertaken in biobanking to study disease are also giving rise to new disease categories and stratifications giving rise to new patient and disease identities. Biobanks have also been complicit in engendering various notions of race and ethnicity.

### 3. STABILISED BIO-OBJECTS

- Stabilised bio-objects both engender value (for future users) and costs (for the biobanks ongoing storage and curation). In this context decisions about pricing strategies become possible, invoking debates around balancing cost recovery, profit, and open access materials.

- The inclusion of biobank donors into the decision-making process through which biobank resources are stored and used works to increase levels of transparency and accountability, which helps to ensure their longer-term sustainability.

- Bio-objects only remain stabilised as long as the infrastructures that supported the processes of bio-objectification remain stable. Adaptions or ruptures to those infrastructures impact the meaning, status and value of the tissue held, for example biobank merger or closure. Such activities can reopen the bio-objectification and bio-identification processes.
CASE STUDIES

NATIONAL GENETIC DATABASES: Transformative possibilities in healthcare delivery

National genetic databases are seen to play a transformative role in the way research is conducted, as well as in the way healthcare delivery is organized and provided. From personalized medicine to new possibilities in carrier screening and health risk identification, national genetic databases pose new possibilities in the ways individuals are managed in the healthcare setting. The ways in which genetic databases become forms of representation of entire populations as cohorts, as well as the focus of medical calculation and intervention are central features of the processes of bio-objectification at the national level. In addition, through processes of personalized medicine, for example, individuals are expected to related to their own health and genetic information in new ways, whereby the responsibility over health and its management become increasingly de-centralized within public healthcare systems. The ways in which national genetic databases collect, store and act upon new genetic findings also plays an important role in the way biobanks can give rise to new forms of governance through their own activities.

STORAGE AND USE OF DRIED BLOOD SPOTS: Blurring the boundaries between care and research

The rise of fast and affordable genomic sequencing technologies is facilitating the re-purposing of biological material that were once collected for health care purposes into valuable research resources. Dried blood spots - or heel prick cards - are routinely gathered from newborns as a part of public health screening programs in most advanced industrialized countries. While the conditions that are screened for - and the length of time that the samples are stored for - varies widely, bio-objectification processes are underway in numerous constituencies to retain and use this material for research purposes that extend beyond the screening programs. What were once boxes upon boxes of unpreserved blood on old cards sitting in basements now stand to become comprehensive population biobanks given the ubiquity of screening programs. These new forms of biobanks are having to re-negotiate the terms under which the biological material are collected as they uncomfortably straddle governance regimes that apply to public health screening and biomedical research. In this way the bio-identification processes through which this kind of biobank identifies itself vis-a-vis other research resources and health care interventions has yet to be resolved or stabilized, calling for innovative governance mechanisms.

HUMAN EMBRYONIC STEM CELL BANKING IN THE UK AND SPAIN: Local cultures shape biobanking practice

The UK Stem Cell Bank was the first publicly funded biobank for human embryonic stem cells. Its success led to other nations adopting the format. However, in translating the governance format across national borders, local cultural differences reshape practice. The UK governance model emphasized distance, lending legitimacy and disengagement through not conducting research itself as the ethically appropriate mode of bio-objectification. In contrast, the Spanish adaption of the format emphasized engagement with scientific research pursuing an internationally competitive research portfolio. This case study demonstrates how contrasting assumptions about how members of the local society judge the work of a publicly visible biobank can shape processes of bio-objectification.

BIOBANK CLOSURE: Bio-objectification undone

Many biobanks are funded through cyclical grant extensions. Our case study of an anonymous disease specific biobank demonstrates the challenges when this funding is not continued. In this case, the breakdown of informatic and governance structures, along with the demise of physical labour and physical environment, undermined the bio-objectification processes that deemed this tissue valuable. Human samples donated by patients informed they were vital for research faced incineration as staff worked to establish new networks of legitimation and new physical infrastructures in which this value could be retained, leading to some rehousing of samples with the majority burnt.
The bio-objects network has identified four related challenges for instantiating RRI practice in the biobanking sector:

**Time and temporality:** Biobanks are, by definition, future-oriented projections requiring consensus about what it is that should be collected, archived, stored, and deposited for future use by sometimes distant future stakeholders. These kinds of investments can be costly for present-day stakeholders or sponsors having to make real-time sacrifices in the interests of projected needs or requirements.

**Governance, ethics and regulation:** Biobanking faces particularly acute challenges in translating questions of responsibility into active reflection and accountability due to difficulties of developing, institutionalising or conforming to codes of conduct and mandatory governance structures.

**Fragmentation and top-down vs. bottom-up:** Without some means of instituting integration, biobanks are likely to develop in ways that fail in the role envisaged for them. They will be vulnerable to weaknesses in the values and moral economies of collaboration and consent that make for successfully innovative life science enterprises.

**Civic co-production:** The RRI agenda reflects the conscious recognition of the need for mutual shaping between technology/science and the social or civic. Differences in scale of biobanks, from large multinational institutions to small local collections require different strategies.

Each of these four barriers to RRI are central both to the developing intellectual and social agenda of RRI, whilst also fundamental concerns or problematics in biobanking. They point to the wider issue of mainstreaing RRI through effective governance and civic co-production. It is clear from our existing body of empirical work that further research is urgently required to develop and pilot mechanisms for accomplishing RRI mainstreaming. Through distinguishing between bio-objectification and bio-identification, this COST action has developed a mechanism facilitating continued modes of articulation and critical engagement with mainstreaming RRI in biobanking and beyond.

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