



# What is in a name?

Biorepositories and tissue banking

Professor Elizabeth Mayne

National Health Laboratory Service and  
University of the Witwatersrand

# Conflict of interest

- Tissue/stem cell banking:
  - Run the tissue immunology (transplantation testing) service at CMJAH/DGMC
- Biorepository services
  - Run the H3 Africa and CLS biorepositories at Braamfontein
  - Science and policy committee for International Society of Biologic and Environmental Repositories
  - Head: Africa committee for European Society of Biological banking

# What is a biobank or a biorepository (are they different from a tissue bank....)

- “The term biorepository usually refers to a facility that collects and stores samples of biological material. These samples could include blood, urine, tissue, cells, DNA, and proteins.” (Centers for Disease control, USA)
- “A **biobank** is an organized entity with a governance in place, responsible for the management of biological resources” BBMRI

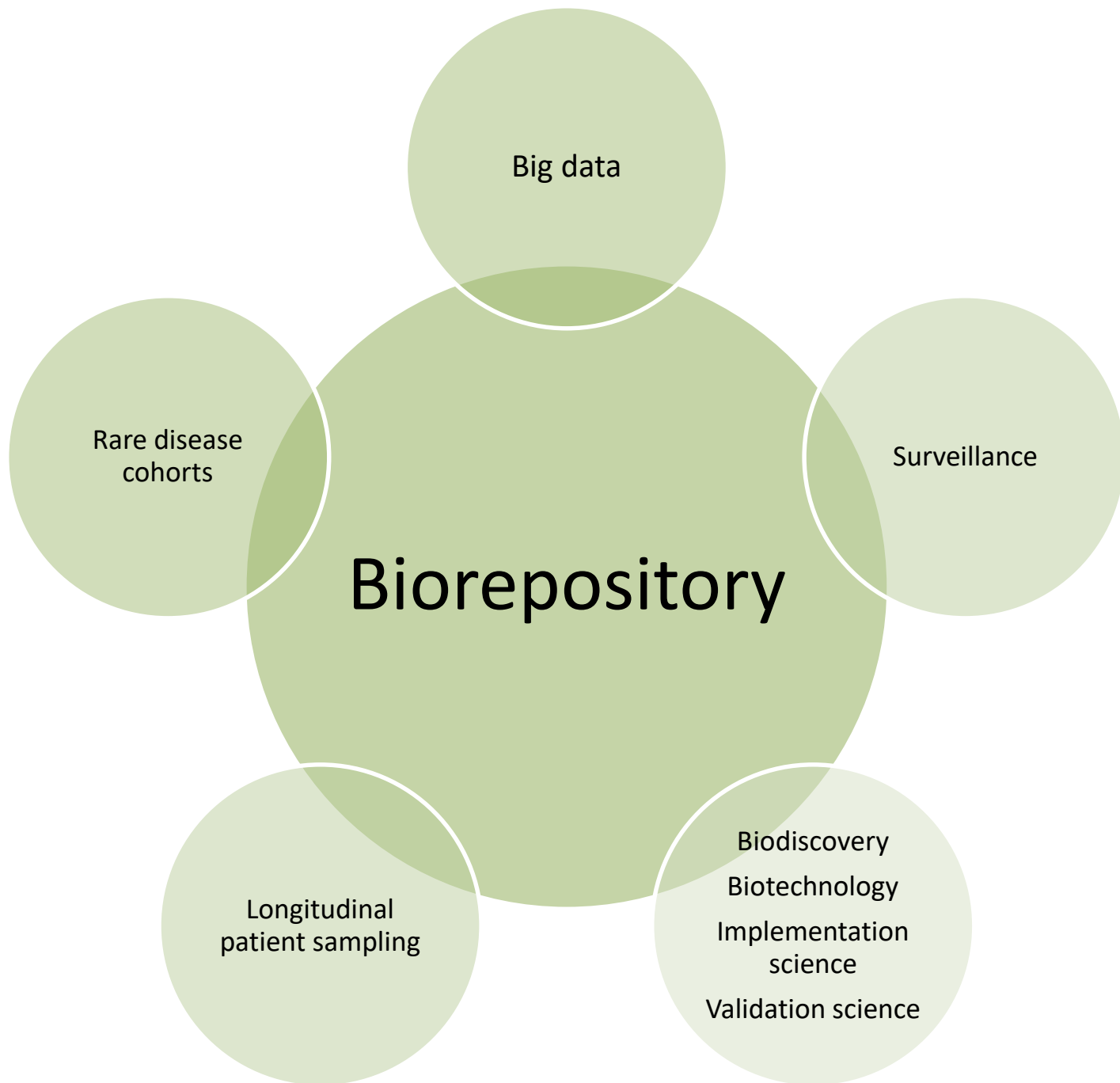
# Issues with semantics

- Who controls, who accesses and who “owns” the samples.
- What samples are covered and by which pieces of legislation, regulations?
- What purposes are allowable?
- If governance is needed, what kind of governance are we talking about?
- Who derives benefit and what is benefit?

Is a biorepository a useful resource ?

# Properly stored and curated samples can be used in ....

- Longitudinal sample collection for biodiscovery
- Strategic partnerships for innovation with biotechnology and pharmaceuticals
- Best practice development for diagnostics and monitoring
- Resource for implementation science



# Case study – the Karolinska Stockholm 3 model for cancer detection

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Dickherber, Tony (NIH/NCI) [E] <anthony.dickherber@nih.gov>  
RE: Liquid biopsy and innovative technologies for cancer diagnostics

To Elizabeth Mayne  
Cc Wendy Stevens

Action Items

It was a plea  
I would be h  
information.  
email first, a  
Also, a quick  
Thanks and I  
Best,  
Tony

 **ELSEVIER**

**European Urology**  
Volume 74, Issue 2, August 2018, Pages 204-210

Prostate Cancer

**The Stockholm-3 Model for Prostate Cancer Detection: Algorithm Update, Biomarker Contribution, and Reflex Test Potential**

Peter Ström <sup>a</sup>, Tobias Nordström <sup>a, b</sup>, Markus Aly <sup>a, c</sup>, Lars Egevad <sup>d</sup>, Henrik Grönberg <sup>a</sup>, Martin Eklund <sup>a, d</sup>

<https://doi.org/10.1016/j.eururo.2017.12.028>

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Referred to by Ola Bratt, Anna Öfverholm  
Re: Peter Ström, Tobias Nordström, Henrik Grönberg, Martin Eklund. The Stock...  
European Urology, Volume 74, Issue 1, July 2018, Pages e9

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# The Stockholm 3 study piggybacked extensively on the Karolinska Biobank

- ~59000 men with prostate cancer were evaluated over 3 years
- All data was curated using a highly sophisticated bioinformatics network


# What about rare conditions ?

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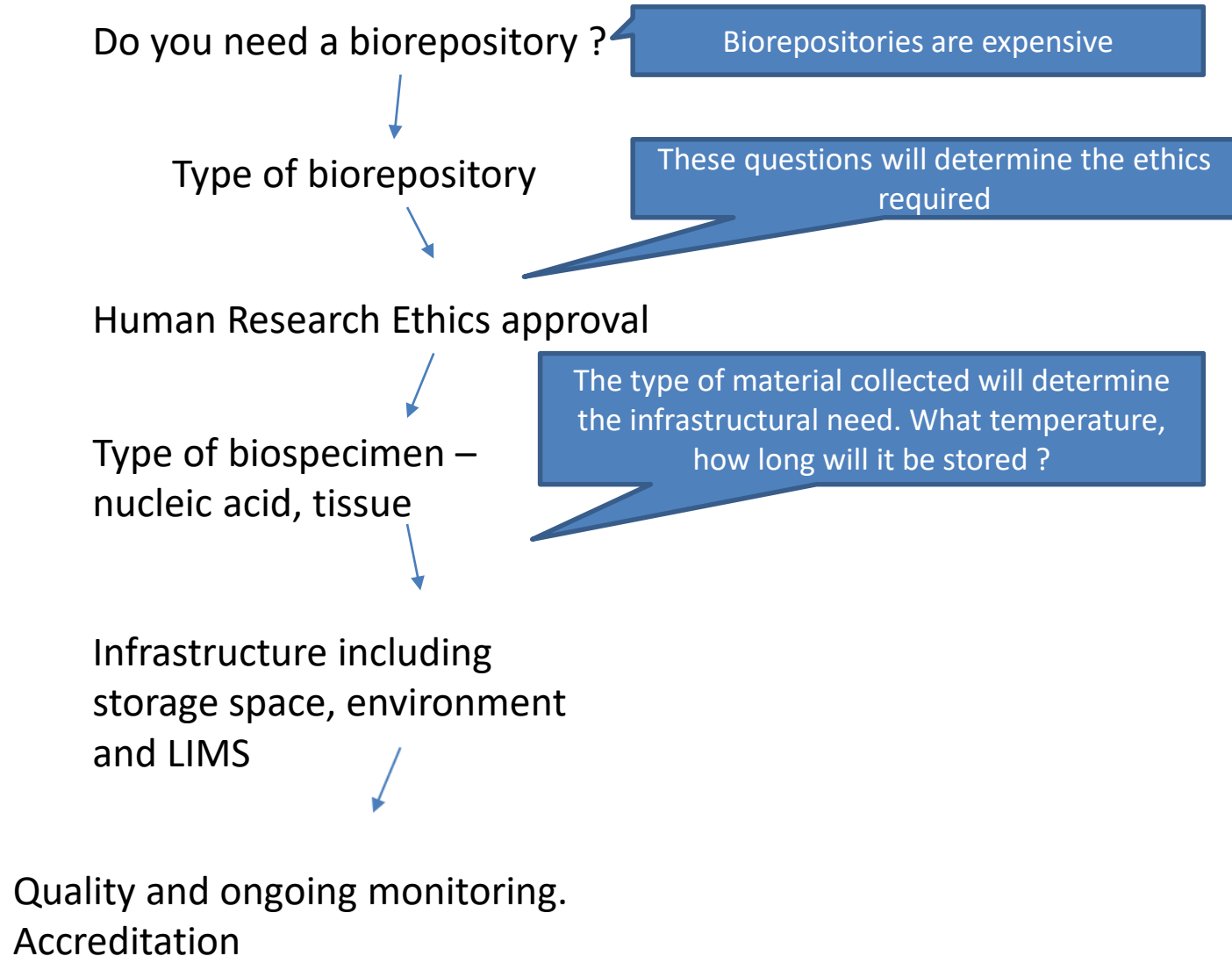
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Establishing a biorepository

# A number of different models exist for research biorepositories

1. Hospital based biorepositories
2. Researcher biorepositories
3. Biorepositories supporting clinical service
4. Population biorepositories
5. Blended models

# When establishing a biorepository...



# The regulatory environment of biorepositories in South Africa

Who guards the guards themselves

It's not worth doing something unless  
someone, somewhere, would much rather you  
weren't doing it. Terry Pratchett

# The National Health Act (No 61, 2003)

2 No. 26595

GOVERNMENT GAZETTE, 23 JULY 2004

Act No. 61, 2003

NATIONAL HEALTH ACT, 2003

54. (1) The Minister may, by notice in the *Gazette*, designate any institution other than an institution contemplated in section 63 as an authorised institution.

(2) An authorised institution may—

- (a) acquire, use or supply the body of a deceased person for any of the purposes referred to in section 64; 25
- (b) acquire or use any tissue lawfully imported or removed from the body of a living or deceased person for any of the purposes referred to in section 56 or 64, as the case may be; 25
- (c) supply any tissue preserved by it to an institution or person contemplated in section 63 for any of the purposes referred to in section 58 or 64; and 30
- (d) acquire, use and supply blood products for any of the purposes referred to in section 56 or 64.

(3) The Minister may, in the notice contemplated in subsection (1), impose conditions in respect of the exercise of a power referred to in subsection (2).

## Human bodies, tissue, blood, blood products or gametes may be donated to prescribed institution or person

63. A human body, tissue, blood, blood products or gametes may be donated by any person contemplated in section 55(a) or 62 to any prescribed institution or person for any purpose contemplated in section 56 or 64(1).

## Purposes of donation of body, tissue, blood or blood products of deceased persons

64. (1) A donation in terms of section 62 may only be made for—

- (a) the purposes of the training of students in health sciences; 40
- (b) the purposes of health research;
- (c) the purposes of the advancement of health sciences;
- (d) therapeutic purposes, including the use of tissue in any living person; or
- (e) the production of a therapeutic, diagnostic or prophylactic substance.

60. (1) No person, except—

- (a) a hospital or an institution contemplated in section 58(1)(a), a person or an institution contemplated in section 63 and an authorised institution or, in the case of tissue or gametes imported or exported in the manner provided for in the regulations, the importer or exporter concerned, may receive payment in respect of the acquisition, supply, importation or export of any tissue or gamete for or to another person for any of the purposes contemplated in section 56 or 64; 25

- (b) a person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product. 30

(2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.

(3) This section does not prevent a health care provider registered with a statutory health professional council from receiving remuneration for any professional service rendered by him or her. 35

(4) It is an offence for a person—

- (a) who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and 40
- (b) to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.

68. (1) The Minister may make regulations regarding—

- (a) the post mortem examination of bodies of deceased persons; 5
- (b) the preservation, use and disposal of bodies, including unclaimed bodies;
- (c) the removal of donated tissue or cells from persons, tissue or cells obtained from post mortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons; 10
- (d) tissue transplants;
- (e) the production, packaging, sealing, labelling, storage and supplying of therapeutic, diagnostic and prophylactic substances from tissue;
- (f) the supply of tissue, organs, oocytes, human stem cells and other human cells, blood, blood products or gametes;
- (g) the importation and exportation of tissue, human cells, blood, blood products or gametes; 15
- (h) the withdrawal of blood from living persons and the preservation, testing, processing, supply or disposal of withdrawn or imported blood;
- (i) the administering of blood and any blood product to living persons;
- (j) the production, packaging, sealing, labelling and supplying of blood and blood products; 20
- (k) the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes;
- (l) the artificial fertilisation of persons;
- (m) the appointment and functions of inspectors of anatomy and investigating officers; 25
- (n) the records and registers to be kept by persons and institutions;
- (o) the returns and reports, including extracts from registers, to be submitted to specified persons and institutions;
- (p) the acquisition, storage, harvesting, utilisation or manipulation of tissue, 30 blood, blood products, organs, gametes, oocytes or human stem cells for any purpose;

# The National Health Act does stipulate some things related to biorepositories

1. Tissue including blood, gametes can be removed from both a live and a deceased donor with consent (and some restrictions)
2. This consent can be rescinded if the tissue has not been used for therapeutic purposes
3. The tissue is donated to an institution not an individual – Clause 54
4. The tissue may be used for medical purposes, teaching of medical students and medical research purposes
5. Commercialisation of tissue or tissue products is expressly forbidden (although payment of costs is allowable)
6. Regulations should govern movement, labelling, packing etc.



# Where does the NHA not provide guidance ?

- Consent is poorly defined as “written consent”
- When is revocation allowed ? Does anyone “own” the samples
- What constitutes acceptable usage in terms of research?
- What about vulnerable populations ? What constitutes vulnerable populations?

Some of these practical issues are  
addressed in a number of  
regulations from the NHA

Not all and certainly not all for  
repositories

# For example, the testy question of ownership

- Who owns the samples in a research biorepository?
  - The donors ?
  - The repository ?
  - The institution ?
  - The third party researcher ?

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## The legal position on the classification of human tissue in South Africa: Can tissues be owned?

S Mahomed,<sup>1</sup> BComm, LLB, LLM; M Nöthling-Slabbert,<sup>1</sup> BA, BA(Hons), MA, DLitt, LLB, LLD; M S Pepper,<sup>2,3</sup> MB ChB, PhD, MD

<sup>1</sup> Special Interest Research Group on Biotechnology and Medical Law of the College of Law, University of South Africa, Pretoria, South Africa

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<sup>3</sup> Department of Immunology, Faculty of Health Sciences, University of Pretoria, South Africa

The ownership of tissue samples donated for medical research is an ongoing subject of dispute. Some advocates assert that patients have ongoing ownership rights in their tissues, including an unfettered right to determine what happens to their tissue sample. Researchers argue that giving patients property rights in their samples will turn the human body and body parts into a commodity and bring research to a halt. The question of the human body as property involves complex and philosophical dimensions. The law displays an uneasiness in making sense of the human body in the context of ownership and property, as the notion of owning oneself (and one's tissues) implies that persons are able to objectify their selves, and in the process become susceptible to objectification by others. The creation of commercial products from human tissue has generated very difficult legal and ethical questions that have no clear, universally accepted answers.

S Afr J BL 2013;6(1):16-20. DOI:10.7196/SAJBL.258

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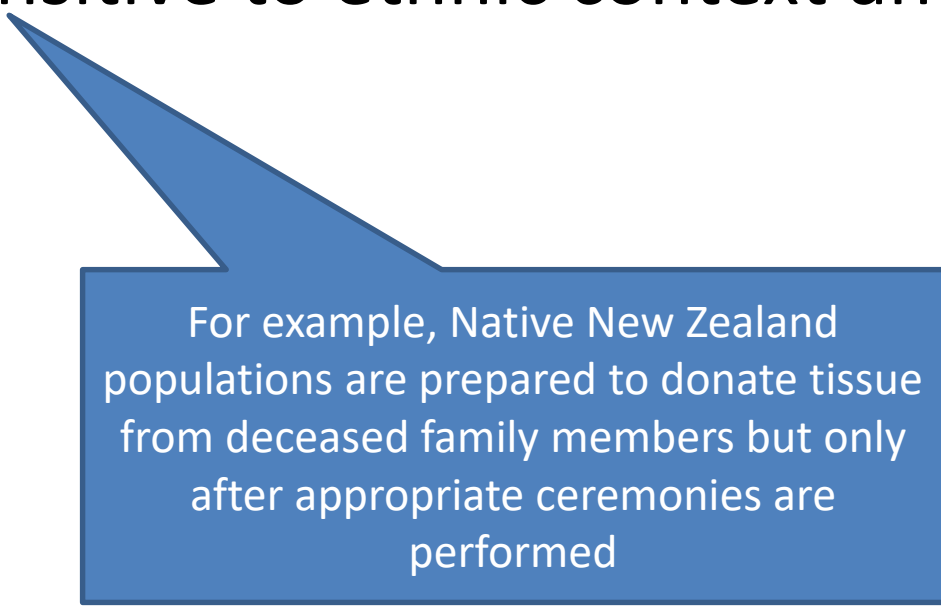
JUNE 2013 VOL 6 NO 1

# And of consent and understanding

- Issues regarding the understanding of the impact of storage (and in a culturally acceptable manner)
- Linked to unequal power relationships in the clinician-patient environment, language and education issues
- How broad is consent and when and how do you re consent ?

# Stakeholder engagement and community engagement are key

- This may involve educational material and counselling
- This should be sensitive to ethnic context and requirements



For example, Native New Zealand populations are prepared to donate tissue from deceased family members but only after appropriate ceremonies are performed

# An important aspect is defining the benefit for storing in a biorepository

1. For the individual – altruism, psychological benefit
2. For the community – healthcare solutions, testing, therapeutic, educational
3. For the researcher – cost, access, rare/numerous samples, capacity building
4. For the country – healthcare, systems strengthening, innovation

# Guidelines exist for tissue banks used for therapeutic interventions in South Africa

This are less well delineated for  
research biobanks



I have a research biobank....

What now ?

# Nothing is more pointless (or expensive) than an unused sample



Biodistributors rather than biorepositories ?

# How do you make a biorepository attractive to researchers

- Scarcity of samples stored
- Types of samples stored
- Marketing
- Continuous collaboration
- Population and prospective collection
- Ease of transferability

# Biopreservation and biobanking (June 2019)

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## **Advancing Professionalization of Biobank Business Operations: Performance and Utilization**

Marianne K. Henderson, Kirstin Goldring, and Daniel Simeon-Dubach

Published Online: 01 Jun 2019 |

<https://doi.org/10.1089/bio.2019.0005>

**Abstract** ▾

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## **Ensuring Effective Utilization of Biospecimens: Design, Marketing, and Other Important Approaches**

Marianna J. Bledsoe and Katherine C. Sexton

Published Online: 01 Jun 2019 |

<https://doi.org/10.1089/bio.2019.0007>

**Abstract** ▾

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## **Commentary on Improving Biospecimen Utilization by Classic Biobanks: Identifying Past and Minimizing Future Mistakes**

William E. Grizzle and Katherine C. Sexton

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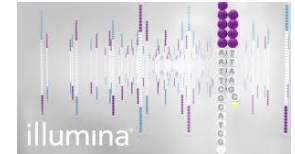
# Collaborations are key – and we need to thank ...

- Governmental:
  - Department of Science and Technology
  - Department of Health
- Institutional
  - National Health Laboratory Service
  - University of the Witwatersrand
  - University of the North-West Province
  - University of Pretoria
  - University of Cape Town
- External Collaborators:
  - National Institutes of Health (2 U24 HG007438-07)
  - Regional biorepositories e.g. Uganda, Nigeria, Stellenbosch
  - ISBER
  - European Society of Biological banking
- Private Public Partnerships
  - Thermofisher
  - Scientific Group
  - Illumina



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us)