



# Banking on Exposure - Companion Animals as Sentinels

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## Agenda

#### **KEY TOPICS OF DISCUSSION**

- Defining Biobank
- ✓ Obstacles in Biobanking of Sentinels
- ✓ Standardization of Biobanking Practices
- **☑** Environmental Specimen Biobanks
- ✓ Strategies and Incentives for Sharing/ Collaboration

## The Definition



A biobank is a facility for the **collection**, preservation, storage and supply of biological samples and associated data, which follows standardized operating procedures and provides material for scientific and clinical use.

Hewitt & Watson Biopreserv Biobank 2013

## Biobanking is NOT

"Biohoards occur when tissue specimens are 'hidden' from the very researchers who have the ability to unlock their value in generating new medical knowledge through translational research"

Catchpoole Journal of Health Services, Research & Policy 2016



## The Obstacles

## **Challenges to Overcome**

What are the obstacles (e.g., scientific, infrastructure, ethical, and financial) to using companion animals as biomonitors?

## Obstacles in Biobanking

Non-standardized biobanking processes

Non-standardized clinical data annotations

Nonuniform bioinformatic systems

Insufficient/ variable consent procedures

Reluctance to share collected biospecimens

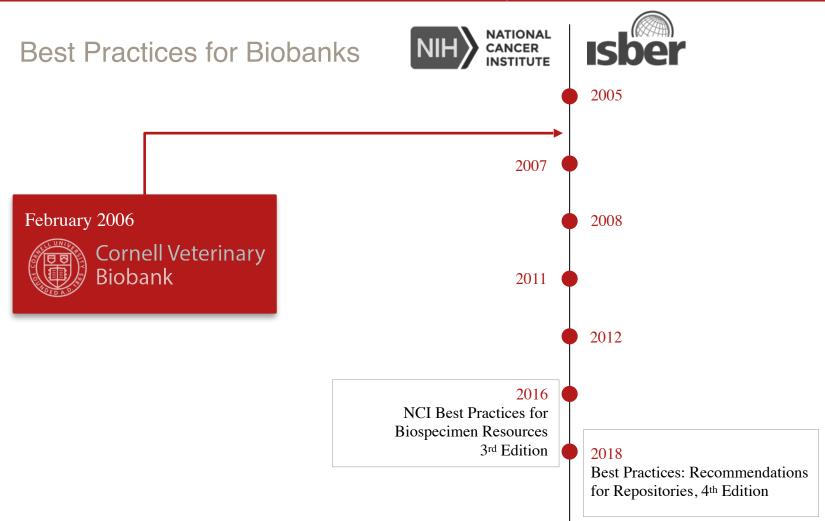
Difficult access to samples from researchers outside institution

Lack of environmental variables or location to link participants to exposure data

## The Standards

#### **Best Practices for Biobanks**

What are the best practices for collection, storage, and analysis of biosamples to assess exposures?





## US Representative

ISO Expert and Delegate





#### INTERNATIONAL STANDARD

#### ISO 20387

First edition 2018-08

#### Biotechnology — Biobanking — General requirements for biobanking

Biotechnologie -- «Biobanking» -- Exigences générales relatives au «biobanking»



Reference number ISO 20387:2018(E)

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# First ISO Standard for Biobanks

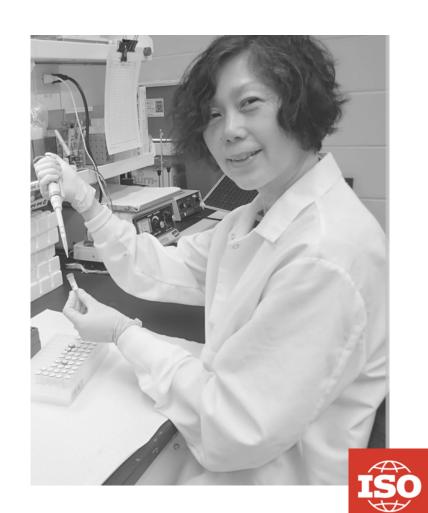
August 2018



# What is Conformity Assessment?

Demonstration that specific requirements relating to a product, process, system, person, or body are fulfilled.

(ISO/IEC 17000:2020)



### Conformity Assessment (CA) Practices

#### FIRST PARTY

Self-declaration of conformity





My products conform to requirements of ISOxxxx

User/ Medical researcher



#### **SECOND PARTY**

Conformity assessment report

#### User/ Medical researcher



I checked your products, and they conform to requirements

Biobank



## THIRD PARTY Certificate



Certification or accreditation body

An external body assessed biobank for compliance with requirements

Biobank





#### **Biobank Accreditation**

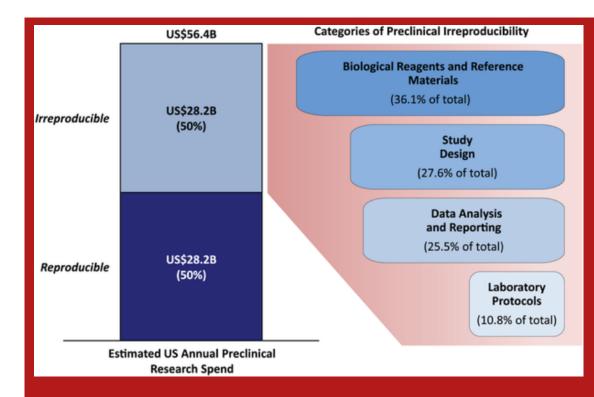


**PERSPECTIVE** 

## The Economics of Reproducibility in Preclinical Research

Leonard P. Freedman<sup>1\*</sup>, Iain M. Cockburn<sup>2</sup>, Timothy S. Simco<sup>2,3</sup>

1 Global Biological Standards Institute, Washington, D.C., United States of America, 2 Boston University School of Management, Boston, Massachusetts, United States of America, 3 Council of Economic Advisers, Washington, D.C., United States of America



<sup>\*</sup> Ifreedman@gbsi.org

#### **Biobank Accreditation**

"...economic research also has shown that **standardization** and **auditing** of biological materials—through biological resource centers—can enhance cumulative production of scientific knowledge by improving both **availability** and **reliability** of research inputs."

Freedman, Cockburn, et al. PLOS Biology 2015

American Economic Review 101 (August 2011): 1933–1963 http://www.aeaweb.org/articles.php?doi=10.1257/aer.101.5.1933

Climbing atop the Shoulders of Giants: The Impact of Institutions on Cumulative Research

By JEFFREY L. FURMAN AND SCOTT STERN

## **Biobank Accreditation**



Assurance of technical competence



Harmonization of procedures



Control of preanalytical sample variations



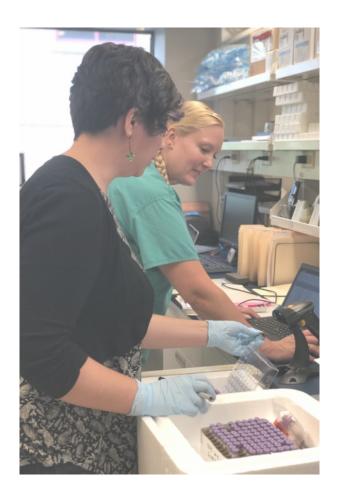
Interoperability among biobanks



Documentation of processes for specific intended purposes (FIP)



**Accuracy**, **Comparability** and **Reproducibility** of research results







# First Biobank in the World accredited to ISO 20387



## Biobanking for Biomonitoring

Towards Harmonized
Biobanking for
Biomonitoring:
A Comparison of Human
Biomonitoring-Related and
Clinical Biorepositories

Lermen, Gwinner, et al. Biopreserv Biobank 2020





## The Biobanks

## **Environmental Specimen Biobanks**

Are there opportunities to promote sample sharing and collaboration to advance research on the role of companion animals as sentinels for predicting environmental exposure effects?

## **Environmental Specimen Biobanks**









Former National Biomonitoring Specimen Bank (NBSB), established in 1979 and Marine ESB, established in 2002

## **Environmental Specimen Biobanks**





Specimen Collection



Pass-through from TAMU to Cornell



Accessioning



Processing and Storage

## **Environmental Specimen Biobanks**



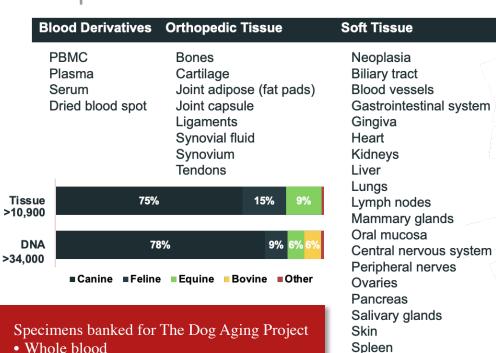






Cornell's Signature Program of Postmortem Tissue Collection

43 minutes Average PMI Biospecimens in the Cornell Biobank

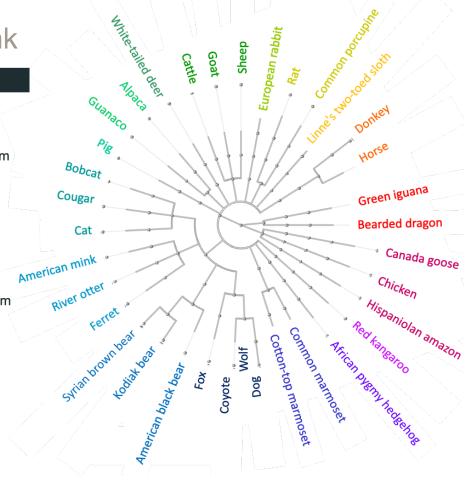


Testicles

Uterus

Thyroid glands

- Serum
- Plasma
- Live PBMCs (peripheral blood mononuclear cells)



## The Incentives

## **Working Together**

What incentives are needed to encourage sample sharing and collaboration? What infrastructure and resources are needed? Which groups need to be engaged?

## Strategies and Incentives

#### Biobankers

- Infrastructure Support
- Risk Management Plan
- Incentives to Standardization
- Biospecimen Science Funding
- Marketing/Communication Initiatives (to promote utilization)

#### Researchers

- Specimen/Data Locator
- Standardized Specimens/Data
- National Environmental Specimen Program
- Marketing/Communication Initiatives (to promote awareness)









## Banking on a New Understanding



Biobanks for
Environmental Exposure
Same household
canine-human collections





## Will you join us?

