

BIOBANKING BEST PRACTICES

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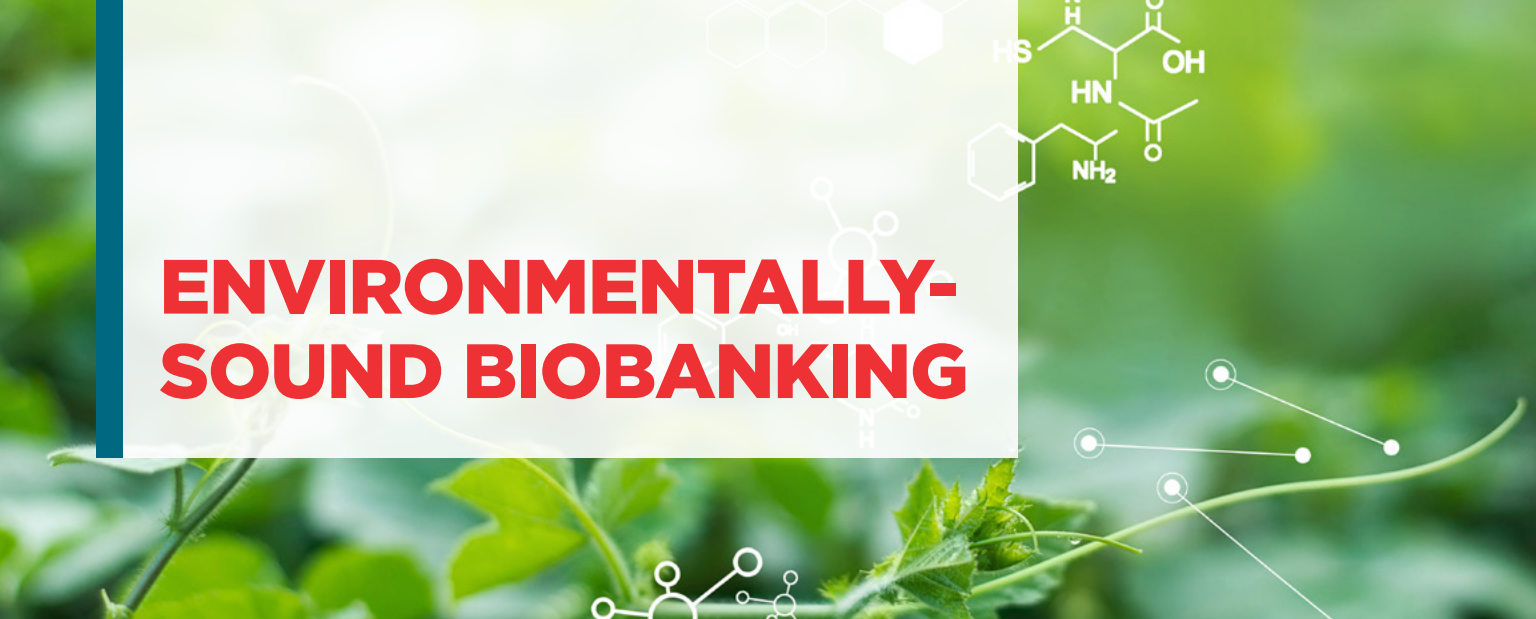
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ENVIRONMENTALLY-SOUND BIOBANKING

Biobanks differ from other large-scale health research settings because although human biospecimens are abundant resources, they are often collected but then never used. Furthermore, each specimen requires unique, low-temperature storage solutions. As such, sustainability is challenging for the discipline of biobanking for two major reasons: diversity in the biobanking landscape and a lack of active sample analysis.

Solutions for Operational Sustainability

In general, biobanks require a lot of energy. A single ultra-low temperature freezer may use the same amount of energy per day as a typical household. In recognition of this, many companies now offer more environmentally sustainable equipment, including freezers intended to minimize energy consumption and tools for manufacturing procedures designed to lessen waste.

Concurrently, biobank scientists are considering their sample management practices. In terms of sustainability, this particularly references sharing existing banked samples. Common sample management systems allow easy sample sharing between sites while sound sample storage practices help ensure that samples are disposed of when needed.

My Green Lab Ethos

[My Green Lab](#) certification is the worldwide standard for laboratory sustainability

best practices. The organization certifies labs in a variety of sectors, including biobanks, academic institutions, government labs, hospitals, pharma, and biotech companies. To become My Green Lab certified, biobanks undergo a baseline assessment and then implement recommended changes to reduce the environmental impact of their work. Once certified, the process can be repeated for continual improvement and higher certification levels.

Researchers may use the My Green Lab accountability, consistency, and transparency (ACT) label to compare and select sustainable products. The ACT label provides information about the environmental impact of manufacturing, using, and disposing of a product and its packaging.

“My Green Lab certification is the worldwide standard for laboratory sustainability best practices.”

Sample Collection Conscientiousness

Another potential waste of resources involves sample collection and usage. If unique specimens from patients are stored but seldom used, it is detrimental to the environment because resources like electricity and plastics are used to store the sample. Furthermore, this practice does not benefit the patient. Responsible sample collection strate-

gies should align with all stakeholders' intentions and actions—for example, patients should be aware of and consent to the use of their clinical data and specimens to avoid the pitfalls and environmental expense of disposing of unique samples.

Disposing of mislabeled or unused samples requires substantial quantities of energy to comply with required safety precautions. Good sample collection practices and exit-policies that require departing researchers to inform remaining staff of the details of their stored samples help reduce energy waste.

The Thermo Scientific™ TSX series ultra-low temperature freezers feature V-drive adaptive control technology that minimizes energy consumption without sacrificing sample security.

These use non-hydrofluorocarbon (HFC) refrigerants manufactured in a facility that has achieved zero waste to landfill, minimizing the environmental footprints for both manufacturing and operating the freezers.



A FOCUS ON ONCOLOGY: BETTER BIOBANKING WORKFLOWS

Biorepositories containing blood samples and formalin-fixed and paraffin-embedded (FFPE) or fresh frozen human tissues from patient-derived tumors are pivotal resources for translational cancer research. Optimal sample collection practices, storage conditions, and well-designed studies are key to successful downstream experimental use.

Sample Preservation for Oncology Research

Researchers and clinicians obtain hundreds of clinical samples each day that are used for diagnostic and treatment-monitoring purposes. A large proportion of these samples originate from surgical tumor resections. Scientists routinely fix these tissue specimens as FFPE blocks, the gold standard material for histological and immunohistochemistry analysis. Alternatively, scientists flash-freeze samples in liquid nitrogen for future use in next-generation sequencing (NGS), proteomics, and metabolomics assays. The size of suitable tumor specimens usually ranges between 0.5 and 8 cm³.¹ Researchers also routinely collect blood samples, both with and without ethylenediaminetetraacetic acid (EDTA), that are often aliquoted into 384-well plates alongside serum samples before being frozen.

Researchers increasingly turn to patient-derived 2-D and 3-D in vitro cell models; these models retain important features of the original human tumors

and have emerged as relevant tools for more dynamic clinical and experimental analyses of cancer. In vitro cell models may be used for drug profiling, patient-derived xenograft (PDX) modeling, and molecular biology research.¹

Common Sample Collection Timepoints

Biobanks store samples from entire cancer or treatment studies, and samples may be stored for years before they are used in research. Typical collection points fall before cancer treatment (i.e., FFPE and frozen tumor tissues or blood samples with and without EDTA), blood samples immediately after treatment and at 6, 12, and 18-month timepoints, and frozen biopsy samples after treatment in poor responders or if disease progresses.²

“Biobanks play a vital role in personalized translational cancer research.”

This results in large numbers of samples per study. As such, well-organized biobanks are imperative for cancer research.

Standardizing Workflows

Early biorepositories at academic institutions consisted of -20°C/-80°C freezers or liquid nitrogen tanks where scientists manually load and retrieve samples. There was no uniform standard for managing samples. As sample and data

types and numbers have increased over the last decade, researchers have begun to standardize sample management globally. Furthermore, automated liquid handling technologies are becoming the norm. Automated systems process, store, annotate, and track samples in systematic ways, enabling cancer researchers to better collect and collate information about diagnoses and treatment strategies.

Some points to consider when creating biorepositories for cancer research include using high-quality, contaminant-free disposable sample collection containers, ensuring secure and traceable tubes, vials, and plates that are suitable for high-throughput downstream processing, employing fast liquid handling technology for reproducibility and preventing sample loss, degradation,

or contamination, controlling sample cooling and freezing using appropriate tools and equipment, and automating data management, sample records, and chains of custody.

Working in Harmony

Biobanks play a vital role in personalized translational cancer research. Wide variation in collection methods, and pre-analytic variations in processing

and bio-specimen storage result in irreproducible data. For example, genomics studies and transcriptomic analysis (e.g., microarrays/PCR) depend on sample stability and RNA integrity, hence even small temperature changes in collection, processing, and storage can affect results.³ As multi-center collaborative studies become the norm, harmonizing biobanking standards is vital. Many agencies recognize the importance of harmonizing human biological specimen biobanking. For example, The Cancer Genome Atlas (TCGA) project noticed problems with inconsistent sample quality.^{3,4}

Adapting and applying the current established best practices from some national institutes, such as the National Institute of Health/NCI's Biorepositories and Biospecimen Research Branch Best Practices for Biospecimen Resources⁵

and the World Health Organization International Agency for Research on Cancer Common Minimum Standards and Protocols for Biological Resource Centers Dedicated to Cancer Research,⁶ will help to improve harmonization processes for biobanks, raising the overall quality of cancer research.

Lab information management systems (LIMS) help researchers overcome collaboration problems and any issues related to sample processing. Thermo Scientific LIMS for biobanks and biorepositories delivers flexibility, adaptability, and stability for cancer researchers worldwide.

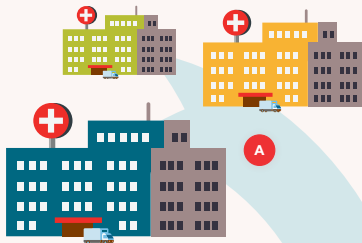
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Biobanks and COVID-19 Vaccine Development

Since the beginning of the COVID-19 pandemic, numerous biobanks have emerged to facilitate studies of the disease, how it spreads, and why some people are more susceptible than others. One major goal of such research is to find a vaccine to protect against COVID-19. The way that samples are collected and stored for viral vaccine research has consequences on downstream research; bad samples lead to bad research. Using best practices for collecting and processing virus samples ensures that biobanks do not become a roadblock in the vaccine creation workflow.



Biobanked samples include nasopharyngeal or oropharyngeal swabs, serum, blood, nasopharyngeal aspirates, bronchoalveolar lavage samples, and tissues from biopsy or autopsy.

Wear PPE and follow CDC guidelines for sample collection



Antigens in the samples may include virus-like particles, weakened viruses, or other harmful substances.



Investigational New Drug (IND) Application



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Phase One

Phase Two

Phase Three

Approval and Biologics License Application (BLA)

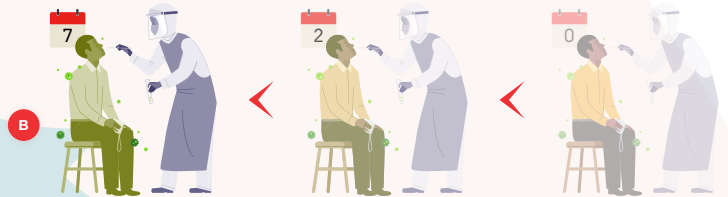


A Multiple collection centers

Biobanks provide sample collection procedure training to clinicians.

B Sample collection on a set schedule

Physicians collect samples at specified times, for example, when patient enters the hospital, and on days two and seven after admission.



C Shipment to a centralized biobank

Ensure that all researchers have fair and transparent access to the biobank's data and samples.

D Exploratory research

Academic and governmental scientists identify natural or synthetic antigens in biobanked samples that might help prevent or treat disease and develop these into potential vaccines.

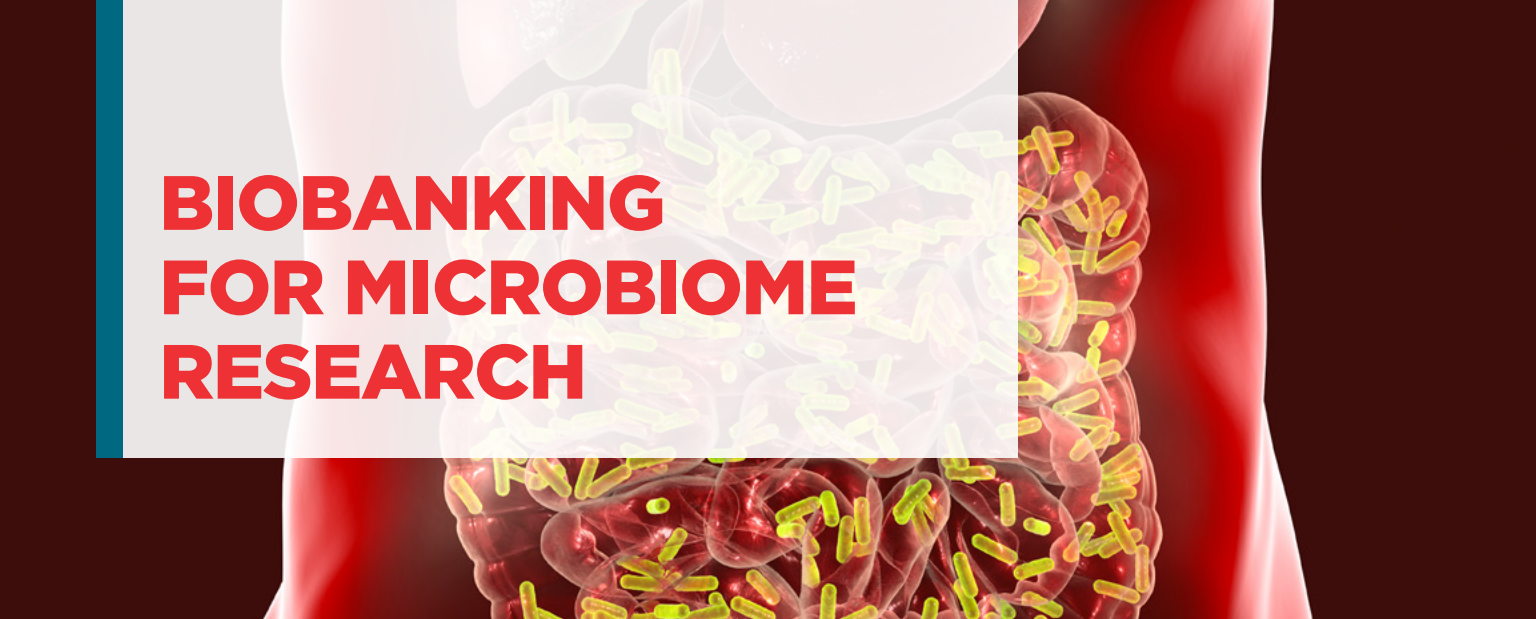
E Pre-clinical research

Researchers use tissue-culture, cell-culture, and animal testing to assess the safety of a candidate vaccine and its immunogenicity.

F Clinical trials

Scientists assess the candidate vaccine's safety, determine the type and extent of immune response it elicits, and optimize the dose, immunization schedule, and delivery method.

G Vaccine distribution



BIOBANKING FOR MICROBIOME RESEARCH

Biobanks of human microbiota and their associated genetic information are becoming valuable health resources. However, this research area requires unique ethical and social considerations, some of which differ from those faced by biobanks that store human tissue or blood samples.

In Sync with Symbionts: Researching the Microbiome

In 2007, the National Institute of Health (NIH) launched the Human Microbiome Project (HMP), which comprised a number of member organizations and repositories connected to a central data repository known as the Data Analysis and Coordination Center (DACC), which set the stage for microbiome research. Scientists studied the microbiome's effects on human health and disease using emerging technologies. These included high-throughput methods and DNA sequencing to characterize the microbial communities that inhabit the human body and explore the relationships between the microbiota and their human hosts. A surge in microbiome research followed completion of the HMP, leading to the creation of microbiome-specific biobanks with exclusive sample and data storage requirements.

Unique Specimens, Unique Storage

Samples biobanked for human microbiome research include dead skin, feces,

saliva, sputum, and urogenital tract, nasal, and cheek swabs. In general, scientists flash-freeze each specimen upon collection and store at -20 or -80°C for future sequencing and genomic analyses.

In particular, collecting and storing gut microbes in biorepositories along with their genetic and metabolic profiles is becoming increasingly important for researching therapeutic approaches

metadata collection requires a hypothesis-driven approach, whereby scientists design questionnaires for data collection based on target outcome, literature reviews, and specific characteristics among populations of interest.² For example, researchers involved in the HMP instructed coordinators to record clinical metadata in a consistent method, using set data formats, for establish-

“Collecting and storing gut microbes in biorepositories along with their genetic and metabolic profiles is becoming increasingly important for researching therapeutic approaches for a wide range of diseases.”

for a wide range of diseases. Such “stool banks” have already shown some promise for treating patients with gut disorders, especially those infected with *Clostridium difficile*.¹

Since there are many host and environmental factors that influence the gut microbiome, clinical metadata collection is complex. Scientists consider age, gender, ethnicity, geography, occupation, human body measurements, diet, drug and probiotic use, supplements, bowel habits, antibiotic use, surgery history, family structure, and even pet ownership. Yet, because environmental factors can rapidly affect the gut microbiome, it may be impractical to record all possible microbiome-associated clinical data. Thus, the optimal strategy for

ing inflammatory bowel disease multi-omic datasets.³ In addition to microbes, human microbiome research samples contain human cells or DNA. The HMP required metagenomic data to be deposited into a public open-access database, while potentially identifying data, such as clinical or human DNA data, go into a controlled-access database.⁴

Bioethical and Social Considerations

Due to the symbiotic relationship between the microbiome and the human host, biobanking human microbiome samples raises new challenges and further complicates debates on the ethical, legal, and social issues (ELSI) of biobanking. From a bioethical perspective,

it is not clear whether human microbiome specimens should be categorized as part of or separate from the human body.⁵ Samples including feces, saliva, and dead skin may be considered waste, but the designation is complex. For example, at the Toronto cystic fibrosis (CF) lung microbiome biobank, sputum samples from adults comprise extra samples that are provided after the patient consents at each clinic visit. In contrast, CF sputum samples from children collected at the Hospital for Sick Children represent excess material from routine microbiological testing, which would have been discarded following testing.⁴ As such, scientists involved in biobanking should treat human microbiome research samples with the same privacy and confiden-

tiality safeguards as any other human tissue samples.

Thermo Fisher Scientific offers several solutions for microbiome analysis, including advanced next-generation sequencing and The Axiom™ Microbiome Array. The array enables the detection of all known microorganisms in a sample with species- and strain-level identification in a single, scalable assay. The proprietary photolithographic arrays help ensure fidelity and consistency across manufacturing batches, with designs available as long as required.

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