The International Society for Biological and Environmental Repositories Presents Abstracts from Its 2021 Annual Meeting

Connect and Collaborate through Biobanking: Powering Innovation and Discovery

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The abstracts that follow demonstrate the broad range of timely issues addressed in the contributed oral and poster presentations at ISBER’s virtual 2021 Annual Meeting.
ORAL ABSTRACTS

O-01  Effect of Ascorbic Acid on Metabolic Status, Lipid Peroxidation, Antioxidant Activity and Quality of Frozen Indian Red Jungle Fowl (Gallus gallus murghi) Semen

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Background: Ascorbic acid is a natural antioxidant found in semen to balance the oxidative stress and improves the semen quality and fertility in various species. It has been noted that concentration of vitamin C for optimum semen quality greatly varies among species. To our knowledge, ascorbic acid has never been evaluated in extender for improving semen quality and fertility of Indian red jungle fowl. The study was designed to elucidate the effect of ascorbic acid on freezeability of Indian red jungle fowl (Gallus gallus murghi) sperm.

Methods: Semen was collected from eight cocks and qualified semen ejaculates having motility >80% were pooled and divided in five aliquots and diluted with red fowl extender (1:5) at 37°C having ascorbic acid 0.0 mM (control), 2.0 mM and 4.0 mM. Diluted semen was cooled to 4°C @ -0.275°C, equilibrated for 10 minutes after the addition of 20% glycerol, filled in 0.5 mL French straws, kept over LN2 vapors for 10 minutes and plunged into LN2 and stored at (~196°C). Sperm motility and viability were assessed at post dilution, cooling, equilibration, and freeze-thawing stage. Sperm metabolic status, antioxidant potential, free radical scavenging activity and lipid peroxidation were studied at post dilution and freeze-thawing stage.

Results: Sperm motility did not differ (P>0.05) in extenders having different concentrations of ascorbic acid and control at post dilution and cooling stage. Nevertheless, higher (P<0.05) sperm motility was recorded in extender having ascorbic acid 2.0 mM compared to 1.0 mM and 4.0 mM ascorbic acid and control. Sperm viability was recorded higher (P<0.05) in extender having 2.0 mM ascorbic acid compared to 1.0 mM and 4.0 mM ascorbic acid at post dilution, cooling, equilibration and freeze-thawing. Sperm metabolic status, total antioxidant potential and free radical scavenging capacity were recorded higher (P<0.05) with ascorbic acid 2.0 mM compared to 1.0, 4.0 mM ascorbic acid and control at post dilution and freeze-thawing stages. Lipid peroxidation in sperm and seminal plasma were recorded lowest (P<0.05) in extender with 2.0 mM ascorbic acid. Fertility rates were recorded higher (P<0.05) with extender 2.0 mM ascorbic acid compared to control.

Conclusions: It is concluded that ascorbic acid 2.0 mM in extender improve motility, viability, metabolic status and fertility of frozen Indian red jungle fowl semen through enriching antioxidant activity and ameliorating lipid peroxidation.

O-02  Biobanking in the Era of COVID-19: Ethical and Governance Challenges

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Biobanking is likely to be a crucial element of the medical and public health response to COVID-19 and future pandemics. The storage and distribution of samples and data are vital for 1) collecting and analyzing biospecimens from patients for COVID-19 related research and 2) may become increasingly important as a resource to maintain other kinds of biomedical research as regular recruitment for clinical studies becomes more difficult during a pandemic. Nevertheless, biobanks face a number of unique ethical, social, and governance challenges during COVID-19 that may require new practices and policies to maintain their work and meet the needs of researchers, donors, and other biobank stakeholders. These challenges may be experienced by both new biobanks created explicitly for COVID-19 related research, and existing biobanks. Additionally, these challenges may be further complicated by the need to balance public health surveillance uses of samples and data with the clinical research uses of biobank resources.

To address these issues researchers at Case Western Reserve University, University of Louisville, and University of North Carolina in partnership with International Society of Biological and Environmental Repositories (ISBER) Ethics and COVID19 TaskForce created a survey to assess the ethical/governance challenges of biobanking during the COVID-19 pandemic, explore the ethical challenges associated with creating new COVID-19 biobanks, and address needed resources for addressing the ethical challenges of COVID-19 biobanking. This talk will present the findings from our COVID19 ELSI survey and discuss how the results may better inform biobanking practices and policies. We believe that a better understanding of the experiences and needs of biobanks will help inform the development of best practices/policies for maintaining biobank operations and address the needs of existing biobanks and new COVID-19 related research resources. Overall, we will discuss how our findings will inform ISBER policies and guidance regarding biobanking best practices, identify areas of need for...
maintaining biobanks during a pandemic, and benefit ISBER members and the broader biobanking community by providing practical strategies for addressing emerging ELSI issues related to the pandemic.

O-03 Consenting Trends During a Pandemic: How COVID-19 Has Affected Clinical Research
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Background: Hospitals worldwide have been severely impacted by the COVID-19 pandemic resulting in adjustments to clinical and research endeavors such as postponement of elective surgical procedures and remote working for non-essential staff members. The BioRepository and Precision Pathology Center (BRPC) plays a vital role in clinical research at Duke University by biobanking tissue and facilitating biospecimen collections from eligible patients.

Methods: Data were retrospectively analyzed in order to understand the impact of COVID-19 on clinical research. Two separate time periods were evaluated during COVID-19 (2020) and pre-COVID-19 (2019) and consent events were compared to evaluate the effects of COVID-19 on clinical research.

Results: A total of 103 consenting events were recorded in the pre-COVID-19 group from 03/16/2019 to 05/14/2019, with an overall success rate of 95.1%. The same dates in 2020 with peak COVID-19 impact recorded 6 consenting events with an overall consent success rate of 100%. A total of 369 consenting events were recorded in the pre-COVID-19 group from 05/15/2019 to 10/31/2019 with an overall success rate of 94.3%. The same dates in 2020 representing an adjusted workflow yielded 297 consent events with 91.2% success rate. There was a 94.2% and 19.5% decrease respectively in patients consented for participation in tissue biobanking and clinical trials during the peak COVID-19 and adjusted workflow COVID-19 period.

Conclusion: Postponement of elective surgeries from mid-March to May resulted in a precipitous decline in consenting events, the long-term impact of which needs to be investigated further. BRPC effectively changed the workflow and implemented new consenting procedures accommodating the COVID-19 restrictions, and staff and patients’ safety needs. BRPC provided consultative services to all labs receiving procurements from eligible patients.

O-04 HLA Typing From Dried Blood Spots Using Lifecodes SSO Typing Kit
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Introduction: The Human Leukocyte Antigen (HLA) genes play a key role in the adaptive immune response and have been shown to be associated with several infectious and autoimmune diseases, cancer and vaccine response. In clinical settings, HLA is used for matching donors and recipients in transplantation. EDTA blood is considered to be the most appropriate sample type for HLA typing. Blood samples require infrastructure for processing and maintaining the cold chain, however, that is often lacking in lower income countries. Dried blood spots (DBS) are an attractive alternative. DNA can be extracted from DBS and used for genomic analysis such as HLA typing. The aim of this study was to evaluate the use of DBS as an alternative sample type for HLA genotyping.

Methodology: Samples were received for typing from a study based in Zimbabwe approved by the Medical Research council of Zimbabwe (MRCZ/A/2282). DNA was extracted from the DBS using the QIA & DNA Mini Kit and quantified using the NanodropTM 2000 spectrophotometer. HLA class II DQA/B, DRB1,3,4 and 5 alleles were amplified using Lifecodes SSO™ typing kit.

Results: Large variation was observed in both DNA quantity & purity (260/280 ratio, 1.01-2.31) of the extracted DNA. Despite this, the extracted DNA concentrations ranged from 4.3–159.2 ng/µl; in most cases, this was sufficient for HLA typing. Successful typing of 54 DBS was achieved for HLA DQA/B, DRB1,3,4 and 5 using low concentration of DNA obtained from one 3 mm disc of DBS.

Conclusion: This is the first study that utilized DBS as a potential sample for HLA typing. Although concentrations and quality varied amongst the samples, 54 samples were successfully typed at all Class II HLA alleles. DBS can be shipped at ambient temperature and can also be stored at ambient temperature.

O-05 Coordinating COVID-19 Tissue Procurement from Autopsy: Challenges and Lessons Learned
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Background: The SARS-CoV-2 pandemic has, according to the CDC, infected over 12 million patients in the United States, and over 250,000 in the United States have died of COVID-19. In response to a need for clinically isolated samples, the Duke University Health System (DUHS) BioRepository and Precision Pathology Center (BRPC) collaborated with the Duke Autopsy service to acquire and release tissue samples to investigators.

Methods: Ten weeks prior to COVID-19 positive autopsies, meetings were held to establish standard operating procedures (SOPs) with DUHS researchers, BRPC leadership, pathologists, surgeons, and decedent care regarding safety, tissue procurement methods, and the collection and transportation of specimens. BRPC provided consultative services to all labs receiving tissue to amend IRB protocols, obtain approval from the school of medicine, and ensure compliance with BSL2+ enhancements. Autopsies were performed with two procurement personnel in the autopsy suite under an approved SOP specific to these autopsies.

Results: Three COVID-19 positive autopsies, and 4 normal control autopsies were performed. While prior non-COVID autopsies yielded approximately 20 pieces of tissue, the average COVID-19 autopsy produced over 500. Several procedural adjustments were critical for safety and efficiency.

Initially, investigators altered tissue procurement requests up until the start of the autopsy. A procedural change to lock the procurement request list one-week prior to a case allowed time to assemble a labeled procurement kit prior to an autopsy.
Extensive spatial and time planning was required to accommodate increased personnel and materials required. Among these, an otolaryngologist collected olfactory and nasal tissue endoscopically. Additionally, to meet CDC guidelines for specimen transport, a “clean” technician was required to open and close containers to limit contamination. Furthermore, communication regarding the timing of each portion of the autopsy was key to limiting personnel entering and exiting the suite, decreasing risks of contamination of clean spaces.

**Conclusion:** In comparison to a typical autopsy collection, COVID-19 autopsies require extensive procedural alterations, but yield diverse tissue samples for research that may otherwise be impossible to acquire. Knowledge of the limitations, material and personnel required, and time expectations prior to performing COVID-19 positive autopsies for tissue procurement is imperative for success.

**O-06 Establishment, Implementation and Utilization of a Human COVID-19 Biospecimen Biorepository at UCLA**

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**Background:** We have developed a semiautomated infrastructure to identify remnant clinical fluid samples to support specimen collection for UCLA Institute of Precision Health from patients who have opted in through the UCLA institutional Universal Consent. This system has allowed us to collect unique remnant fluid biosamples for subsequent DNA extraction and genotyping on over 30,000 patients to date. Here we describe the modification of this system to efficiently capture specimens from patients with SARS-CoV-2 causing coronavirus disease (COVID-19).

**Methods:** We utilized a COVID-19 patient registry to identify potential sources of remnant biospecimens. This dynamically linked registry to UCLA Healthcare’s electronic health record system includes all patients who have had at least one resulted COVID-19 PCR or Antibody IgG test. A COVID-19 remnant specimen report is generated three times each week by cross-referencing the COVID-19 patient registry to a listing of all clinical biospecimens scheduled for disposal for the next three days. This report is refined by selecting patients who have had a positive PCR or IgG test result and compared to our current inventory to identify specimens from previously unsampled patients. Additional filtering is performed to track the interval between positive test date and sample collection date, allowing for the collection of longitudinal plasma/serum samples. Through our Biomaterial Tracking and Management System (BTM, Daedalus Software Inc.), reports are generated daily to detect sample collection from onsite and offsite labs, to pull and courier samples to our repository. Whole blood samples are retrieved for DNA, serum, plasma and PBMC isolation. We also initiated the generation of an automated, weekly report from the EHR that alerts us to any autopsies from COVID-19 positive patients for potential remnant tissue samples.

**Results:** From March to November, over 11,700 biospecimens have been collected from 1,300 unique patients, consisting of whole blood, DNA, PaxGene, PBMC, plasma, and serum, and various tissue samples. Over 2,370 biospecimens have been released to approved study teams.

**Conclusions:** We have successfully established a semiautomated infrastructure and workflow to capture annotated specimens from patients infected with SARS-CoV-2 that significantly reduces the chance that specimens may be missed. This allows for the efficient generation of a large number of specimens that researchers can rapidly obtain for study.

**O-07 A Paradigm Shift - Re-purposing Resources and Infrastructure During a Pandemic to Ensure Sustainability**

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**Problem:** The COVID-19 pandemic has disrupted practically all human activities around the world, including, the biobanking research community. In March 2020, in response to the COVID-19 pandemic, all non-essential research activity was halted within the University Health Network (UHN) and in Canada, to protect the community and flatten the curve.

As a core facility at UHN, UHN Biospecimen Services, a biospecimen storage and sample information management group, was deemed essential to expedite COVID-19 research and assist in sustaining essential research operations. UHN Biospecimen Services had to re-purpose existing biobank infrastructure and available assets to centralize resources and answer an institutional call for help in the battle against COVID-19.

**Solution:** In close collaboration with Infectious Disease, Occupational Health and other departments, resources, infrastructure and skill-sets were repurposed to fit the organization’s current needs. For example, a dedicated, Biosafety Level 2 COVID-19 processing laboratory was established. Amidst the clinical and research shutdown, staff were re-deployed across the organization to critical areas, where assistance was in high demand. Over 50 staff have been re-deployed to assist in the newly formed COVID-19 Biobank facility, since May 2020.

Processing COVID-19 samples involves compliance and adherence to established organization’s COVID-19 safety protocols, biobank best practices and high-quality standard operating procedures (SOP) to yield prime biospecimens. New SOPs and guidance documents were developed encompassing such standards. Additional training has been provided to clinic and laboratory staff to ensure they are well equipped with COVID-19 safety procedures during sample collection, transportation, processing and storage. Emergency Response procedures were adapted to fit current and ongoing infection control measures.

**Conclusion:** The implementation of complex and creative strategies to: reduce costs, allocate available resources efficiently and optimize operations to guarantee sustainability, yielded the setup and establishment of a biorepository for COVID-19 research. Adaptability of a biorepository is key to remain fit-for-purpose, sustainable and enable innovation and discovery amidst uncertain climates. UHN Biospecimen Services is able to remain sustainable during this unprecedented time by implementing a visionary approach and balancing financial, operational and social dimensions.
Background: Atrial fibrillation (AF), the most common abnormal heart rhythm requiring therapy, is associated with increased risk for stroke, heart failure, dementia and death. There is increasing evidence supporting the concept that susceptibility to AF is related to race/ethnicity. The Qatar Cardiovascular Biorepository for Familial Atrial Fibrillation (QCBio-AF) overall goal is to identify and phenotypically characterize Middle Eastern families with early onset AF. This study is to present the study design, methodology and preliminary results of QCBio-AF.

Methodology: QCBio-AF is a familial genetic association study aiming to recruit families with early-onset AF members (n=500 subjects). The recruitment was through the Hamad Network hospitals in Doha, Qatar which covers 95% of the population in Qatar. All early-onset AF patients (probands) in HMC were identified. The potential participants were asked to book an appointment at Qatar Biobank where consent, data and sample collection were completed by trained staff. The relatives to these probands were grouped according to proband-relation: offspring from either maternal or paternal proband, and siblings to proband using PhenoTips® software. The recruitment is ongoing.

Results: At present, QCBio-AF has enrolled 18 participants (n=9 males, 9 females) with a median age of 52.5 years (38, 76). Completed data have been collected for 95% of the participants, while all participants provided biological samples for both viable cells and DNA, following Qatar Biobank standards. In total 15 families were identified encountered to 6 different nationalities from Middle East region and the relevant extended pedigrees were collected. The first individual in a family diagnosed with early-onset AF, was defined as the proband, while the first-degree relatives (children and siblings) were defined as associated relatives. The average number of siblings was 7 (SD, 2.8). Probands (n=15) were identified, offspring from maternal proband (n=24) and from paternal proband (n=40) and siblings to proband (n=78).

Conclusion: The present study, with geographical focus in the Middle East provides a valuable resource of information to the wider scientific community allowing the formulation of effective precision medicine intervention for the management of AF.

O-08 QCBio-AF: Qatar Cardiovascular Biorepository for Familial Atrial Fibrillation

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Background: The unprecedented global spread of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) and its resulting disease (COVID-19) is characterized as one of the greatest global public health crises of the recent decades. The COVID-19 Biorepository is Qatar’s National project aiming to support the extraordina...
risk of further spread of the virus. New treatments, in which a dual approach: accelerating the development of new treatments and screening and identifying molecules that could work against the virus, using advanced modelling and computing techniques, and development of new vaccines. A COVID-19 data portal was created. COVID-19 industrial cluster response portal was established. SMEs portal involved in COVID-19 was supported. Research infrastructure services to support the fight against COVID-19 were originated under umbrella of European Commission. The most important activities and actions will be presented.

Conclusions: The pandemic has changed all aspects of biobanking life and science, accelerated new techniques and technologies how to collect, process and store COVID-19 samples, basic research, research in the field of new vaccines, therapeutic procedures, implementation of IT solutions. Pandemic supports the international collaboration and samples and data sharing, and creation of new types of virtual biobanks.


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Problem: Diagnostic development and validation require consistent availability of well-characterized, high-quality biospecimens. 
There is a great disconnect between biobanks and industry or developers’ needs, leading to slow reaction to outbreaks and missed opportunities for sample access and sharing. Long-term sustainability and fit-for-purpose collections are still unresolved biobank issues, even more relevant when activities are performed in LMICs (low- and middle-income countries) who are often reticent to distribute samples due to legal/ethical barriers and mistrust of research and use of samples.

Proposed Solution: Building on its biobank experience focused on infectious diseases in LMICs, FIND has established a strategy for a disease-agnostic, network-based biobank model, adapted to industry needs. The model focuses on:
1) increasing sample visibility and access and
2) empowering research and capacity building in LMICs

The two main components of the model are the FIND Integrated Biobanks (FIB) and the Virtual Biobank Directory (VBD).
The FIB is a network of biobanks for pandemic preparedness that work under FIND’s coordination to conduct collection activities to support diagnostic research, development, and evaluation.

Due to the FIB structure, network sites based in LMICs will be able to rapidly scale-up activities to support both outbreaks and local clinical and research needs. FIND serves as the central coordinator, managing sample requests from external users, and ensures standardization among FIB sites in terms of documentation, operating procedures, infrastructure building, training, and study conduct. Local storage of banked samples and data will be managed within the FIB sites, which will also participate in decision making regarding the use of samples collected at their site.

To enhance the visibility of existing biological resources, FIND created the VBD, a searchable directory of information on collections either hosted by FIND or by other organizations or networks. The VBD is an open-access, free-of-charge tool allowing users and sample custodians to interact on sample transfers without FIND’s intervention.

Conclusion: Both the FIB and VBD are currently being piloted to support FIND’s COVID-19 work.

FIND plans to expand the model to respond to needs within its disease programmes, such as neglected tropical diseases, tuberculosis, malaria, fever, HIV/HCV, and pandemic preparedness.

O-12 Application of Natural Language Processing for Biorepositories

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Statement of the Problem: Biorepositories have been collecting specimen at Baylor College of Medicine (BCM) for over 30 years. Over time, a concerted effort has been made to enhance the annotations of the specimen. BCM biorepositories function in multiple clinical affiliates which have separate pathology and electronic health record software. None of these systems function together and pathology reports are provided in a text format which is not optimal for automated data collection. The challenge is to review, read and extract useful information which would be pertinent for research and then make them accessible in a searchable format. The BCM biorepositories decided to implement natural language processing (NLP) technologies to extract structured pathology data from standard reports.

Proposed Solution: Our proposed solution was to train an NLP pipeline to pick up the files and extract a specific set of data elements which are required elements of a pathology report and are commonly used criteria for selecting research cohorts. We partnered with the University of Texas-Health Science Center who developed the CLAMP NLP tool. This tool provides multiple methods of text analysis in a pipeline for concept mapping, assertion classification, named entity recognition, machine learning, and more. We began by establishing a target data set, creating definitions, and identifying data relationships within the varied pathology report formats. This information was used to build a human annotated corpus. Agreement of this corpus to the data pipeline results had to be achieved to establish a gold standard for training the machine learning model. Once trained, the machine learning model became one of the elements in the NLP pipeline. Iterative refinement of the results from the pipeline improved the subsequent data set. Once the final pipeline reached over 95% agreement with the human annotated data set, the pipeline was built into a Java application and the structured data loaded into a relational database.
O-13  Data Management Tools in the NIST Biorepository
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Asset management in biorepositories has historically been focused on capital assets such as facilities, staff, and freezers. As technical data management tools have improved, data have increasingly become considered an asset to the same degree. Such data can describe the facility, a collection, or any downstream data produced. Breadth and focus can range from pass-through facilities holding minimal data describing samples and their storage, to facilities attached to clinical laboratories where analytical tests are ordered and the results stored. Regardless of the type of data associated with physical collections, ensuring the highest possible data quality is of utmost importance to achieving operational excellence. Commercial software targeting biorepositories helps tremendously and is generally flexible enough to fit the broad array of biorepositories. It cannot, however, fully substitute for robust data quality management and practices; there will always be a gap between data management tool designs and the practical needs of, and direct implementation within, any given repository. Over the last few years, the NIST Biorepository in Charleston, SC, has developed several data-first tools and approaches to specifically address this gap with regard to data quality management. These include (1) data collection tools that capture data more stringently from field or collaborator collection events; (2) workflow curation tools to ensure each process occurs in the same way every time regardless of how much time has passed since the last event needing that workflow; (3) data quality audit practices; (4) data visualization tools to manage capital assets such as freezers; and (5) a tool to conduct physical position audits in a rapid manner. Combined, these tools and associated approaches have greatly reduced data entry errors, accelerated time-intensive data quality activities, and provided at-a-glance insights into the function and status of the biorepository. The general approach, as well as discrete benefits and reasons for the creation of five specific tools, will be discussed. Custom data tools such as these are currently saving the NIST Biorepository over 1,000 hours of staff time annually and highlight the necessity of a technical data manager in modern day biorepositories. This presentation is targeted toward repository managers, data managers, and those interested in improving data quality practices and streamlining biorepository operations.

O-14  ISO 20387 Accreditation, Corrective Actions, and Deficiencies So Far
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The A2LA Biobanking Accreditation Program uses the ISO 20387 standard to promote confidence in biobanking. ISO 20387 contains requirements designed to demonstrate the competence of a biobank’s operation and ability to provide biological material and associated data for research and development. Biobank accreditation is a formal recognition by an authoritative third party of the competence of a laboratory to perform specific biobanking activities including acquisition, collection, preparation, preservation, storage, testing, analysis, and distribution. Much has been learned over the past year after conducting 3 assessments to ISO 20387, especially from the deficiencies cited.

Deficiencies cited by A2LA assessors are where a biobank’s quality management system or adherence to requirements are not being followed and a finding requires corrective action. Deficiencies include objective evidence that a biobank is not meeting a clause in the ISO 20387 standard, A2LA policies, or specific methods used for biobank activities. The corrective action process should aim to prevent the deficiency from recurring by implementing actions. Those actions are to be recorded, and under A2LA policy, submitted with objective evidence that those actions have been executed. From the past two years, the deficiencies cited against currently accredited biobanks range from procedures missing specific items called out in ISO 20387 to technical requirements from specific methods.

Before assessments occur the biobank will need to apply for accreditation. So why accreditation?

Benefits of Accreditation for the Biobank:
- Accreditation by a third party provides credibility to the users of biobanks and establishes a level playing field.
- Use of Accreditation Bodies that are signatories to the ILAC Mutual Recognition Arrangement (MRA) provides a high level of confidence in the Accreditation Body’s competence. This confidence is based on the requirement for the Accreditation Body to undergo routine and rigorous peer evaluations against long-standing international standards for assessing quality.

Attendees during this session will gain an understanding of the A2LA process for conducting an assessment, but more formally understand the deficiency process with A2LA and what is expected from a biobank according to ISO 20387. Attendees will also have an opportunity to review some deficiencies cited so far and how they could be resolved to prevent recurrence to obtain a positive accreditation council vote.

O-15 In Extraordinary Times: Resetting the Bar of Sustainability and Opportunity - Observability of Value for Biobanks
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Statement of the Problem: COVID-19 has been a crisis of extraordinary proportions, causing serious impacts on human health and research. Biobanks are in a key role in facilitating the understanding the SARS-CoV-2 disease and the public health response. This crisis, while highlighting the necessity of biobanks, has exposed the existing and new sustainability challenges, in operational, financial, and social aspects. Also, there have been valuable opportunities for biobanks in research, vaccine, diagnostic and drug development for COVID-19. Being ready and able to adapt to new opportunities is at the heart of a professional biobank.

Proposed Solution: Biobanks must maintain their focus on the basics of their business plan, including vision, mission, strengths, weaknesses, opportunities and threats (SWOT) and risk analysis, and performance metrics. Clarity, of mission, stakeholders, and abilities, allow for the addition of realistic opportunities to their portfolio. The pandemic has presented
opportunities to find innovation in operations, in new stakeholders, and in new observability of their value. Taking on new collections in COVID-19 public health responses is occurring globally and may change utilization metrics for the biobank in the short and longer term. Automation of processes and human capital management may have been forced to evolve during the crisis, and these changes could bring further evolution to the biobank post-pandemic. The availability of vaccines and tests to control the pandemic will likely not decrease the demand for COVID-19 samples for additional research in monitoring of safety, effectiveness, and durability not only for the vaccines and tests but also for drugs to treat COVID-19 disease. In addition, the availability of COVID-19 products will not be uniform across all continents/countries. These factors may create an unbalanced situation, such that the need for samples and data from different parts of the world will be variable.

**Conclusions:** The COVID-19 pandemic has been a disruptive and unprecedented event but, nevertheless, the crisis has been an opportunity for biobanks to show observable value to research communities. This presentation will provide the key focus of sustainability and planning that has provided the ability for successful biobanks to pivot during the pandemic. Discussion will include actual and potential impacts of the pandemic on biobanking, which highlight its observable value to the research community.

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**O-16 QBB Rapid Transformation into COVID-19 Biorepository: A Showcase**

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**Background:** The SARS-CoV-2 virus and the outbreak of COVID-19 disease has been one of the most important global crises on public health. Qatar Biobank (QBB) had to convert and respond to this crisis by providing its services for the collection, processing and storage of high-quality data and specimens for the better understanding and the response to the therapy and survival of COVID-19 disease. In this study we will highlight the challenges, risks and opportunities of QBB during this transformation period.

**Methods:** QBB is CAP accredited and holds ISO certification for Quality Management Systems 9001:2015 and Information Security Management Systems 27001: 2013. These standards helped QBB management to readily adapt by following rigorous processes to effectively convert its operations and facilitate the COVID-19 National project.

**Results:** Within 5 weeks QBB transformed to accommodate a disease/virus-based biorepository. Multi-adjustments had to be implemented at operational level such as: i) QBB IT department developed a highly secured electronic system for the data collection and specimen traceability ii) Clinically trained staff (n = 17) were transferred to different healthcare facilities in order to recruit COVID-19 positive patients; iii) QBB Laboratory designed special collection kit, iv) QBB Medical Review Office (n = 4) and Scientific and Education (n = 2) departments managed the recruitment process, set up the study and provided training to the staff; v) the Communications and Participants Recruitment Department (n = 7) transformed its operations to fit the needs of the COVID-19 initiative. The Research Access Office (n = 6) designed the COVID-19 access portal and supported the project from the purchasing of PPE and other administrative works needed.

**Conclusion:** It is now time to consider lessons learned, as many countries have been affected by COVID-19 outbreak, and to understand that biobanks are an asset for a country and integrate them into a new standard with their sustainability in mind. Qatar Biobank and its network with academic, research and governmental entities is a good showcase.
POSTER ABSTRACTS

Biobank Tools

PA-01 Development and Use of a Mouse Tissue Collection Request and Documentation System
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Proper management of animal sample collection is critical for preclinical testing performance, quality and reproducibility of data. Sample quality in toxicology studies requires a well-designed tissue collection protocol, robust documentation and an efficient sample traceability method. We describe here our successful implementation of a system to request and document tissue sample collection for in-house mouse toxicology studies and preclinical research projects. We leveraged our existing use of the SoftMouse.NET database and software to implement this system. SoftMouse.NET has supported colony management in our vivarium for four years and is specifically used to manage our mouse breeding, mouse study allocation, treatments and necropsies. We decided to extend usage of the SoftMouse.NET platform to also generate and track sample requests, registration, labeling and collection, with the goal of allowing for greater data transparency and business continuity. To accomplish this, our in vivo tissue collection workflow was mapped out and isolated into individual tasks. These tasks were then built into SoftMouse.NET as configurable experiment building blocks. In practice, the scientists arrange these blocks to customize their study tissue collection. Once the study is built virtually in SoftMouse.NET, the biorepository is able to pre-register the samples and track their generation, and the vivarium operators can document sample status at all phases of the project. The software seamlessly assigns a timestamp to each necropsy and each sample collected, thereby enhancing the quality of the animal tissue annotations. We demonstrate that this system has streamlined and optimized our tissue collection process from design to execution to sample storage and distribution, which has guaranteed a well annotated tissue collection.

PA-02 Mapping of Biobanking Guidance Documents Based on Table of Contents and Glossary Analyses
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Biobanks have developed in great numbers throughout the world, reflecting the need for growth in clinical discovery, understanding and implementation of translational research. Documents aiming to harmonize biobanking practices and create a much more aligned, professional field have been created by international organizations (ISBER, ISO and IARC) and provide scientific, operational, ethical, and legal guidelines and standards, taking into account complexities within specific geographical areas or further technical advances such as clinical imaging banks. Each one of these guidelines carries its own inherent background, focus and emphasis. These differences in background (however slight) have the potential to manifest themselves as differences in terminologies, definitions and the emphasis on the advice provided. Thus these areas of divergence are highlighted, explained and codified.

In this article we have compared three crucial international documents in the field of biobanking published within the last three years. As opposed to a whole text to text comparison, the observations described relate to structural comparisons of the texts, as well as the comparisons of the glossaries and the definitions therein. Such a mapping is crucial in understanding which document is most appropriate for each biobanking context, especially as these guidelines are already starting to be adopted by the biobanking community.

Biobanking Profiles

PB-01 Biobank Profile: China National GeneBank
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As the first integrated national gene bank in China, CNGB is committed to support scientific research, public welfare, innovation, and industrial infrastructure construction. Based on the abilities to “read, write and store” genetic information, CNGB serves as an open platform that provides access to and enables exchange and sharing of genetic data and resources to advance the development of the life sciences and bio-economy.

China National GeneBank (“CNGB”) is a non-profit organization supported by the Chinese Government. CNGB has built an integrated infrastructure of “Three Banks and Two Platforms”. “Three Banks” represent the Biorepository, Bioinformatics Data Center and Biological Resource Center of Plants, Animals and Micro-organisms. “Two Platforms” include Digitalization Platform and Synthesis and Editing Platform.

Reading: An automated, informatized platform with petabytes throughput each year, the Digitalization Platform is dedicated to supporting research projects in precision medicine, agricultural breeding, marine development, biodiversity conservation, etc.

Writing: CNGB is building a world-leading writing platform that is capable of synthesizing 10 million base pairs per year. The platform enhances application of synthetic biology and gene editing technologies in natural product biosynthesis, disease diagnosis and treatment, modern agriculture, environment protection and other areas.

Storing: China National GeneBank DataBase (CNGDb) is an integrated platform built for biological data sharing and application. Based on big data and cloud computing technologies,
it provides data services such as archive, analysis, search, data management and scientific databases to researchers around the world.

**EBB (E-Biobank):** EBB bridges the gap between biosample holders and users by aggregating bio-sample and bio-bank information at home and abroad in a standardized method. It aims to create an equal and open environment for sample sharing and enhance reasonable utilization of bio-samples.

**Public Service Platform:** Opening up its scientific infrastructure to the public, CNGB provides public services based on its powerful abilities to “read, write and store” genetic information to support the development of life science research and industry.

**PB-02 Supporting Cancer Research through a Cooperative Human Tissue Network (CHTN): Impact of Collaborative Effort 2019**

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**Background:** CHTN is an NCI-sponsored prospective human tissue procurement program that provides quality human tissue and clinical data to approved investigators. A great variety of anatomic sites, diseases, and standard/custom preparations are procured by six CHTN Divisions to meet investigator requests. Requests that a division cannot completely fulfill quickly enough are networked to the other divisions to get investigators the needed samples in a timely fashion. The Midwestern Division (MWD), based at OSU, assists the other divisions in serving the investigators in their territories.

**Methods:** Counts of samples shipped in 2019 by anatomic site and tissue type (malignant, benign, etc.) and the number of investigators they supported were obtained from the CHTN Tissue Quest investigator management system and Annual Report.

**Results:** The CHTN shipped 16,395 malignant samples to investigators in 2019. This represented 46.4% of 35,361 total samples shipped in 2019 to 623 investigators and does not include other specimen types (disease, normal, benign, indeterminant, or pre-invasive neoplasia). Malignant samples were from 52 different anatomic sites with soft tissue as the most common (2,289, 14.0% of malignant) followed by colon (2,058, 12.6%), breast (2,016, 12.3%), kidney (1,732, 10.6%), lung (1,391, 8.5%), oral cavity (1,064, 6.5%), bone marrow (950, 5.8%), bone (656, 4.0%), ovary (570, 3.5%), pancreas (432, 2.6%), prostate (405, 2.5%), liver (392, 2.4%), bladder (348, 2.1%), blood (339, 2.1%), 1,753 shipped malignant samples were from 38 other sites (10.7%).

MWD shipped 5,472 total samples in 2019 in support of 157 investigators, 97 of which were in other division’s territories. 3,438 (21% of the CHTN’s) malignant samples were supplied by MWD and were from 43 anatomic sites with colon as most common (1,130, 32.9% of malignant) followed by lung (467, 13.6%), oral cavity (358, 10.4%), kidney (350, 10.2%), ovary (200, 5.8%), breast (182, 5.3%), skin (124, 5.3%), brain (87, 2.5%), 540 were from 35 others (15.7%).

**Conclusions:** The CHTN is supporting cancer research with nearly half of 2019 shipped samples being malignant. Additional non-malignant samples are used as controls, etc. in cancer research studies. The availability of MWD-procured samples from various anatomic sites differs from other divisions. Investigations benefit by other divisions procuring when the home division cannot procure enough of the requested tissue.

**PB-03 Adult and Pediatric COVID 19 Mississippi Biobank Collection**

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**Background:** At the University of Mississippi Medical Center (UMMC) has been prepared to take care of patients diagnosed with COVID-19. There are a few studies investigating different aspects of COVID-19. We aim to collect blood samples from adult and pediatric patients with diagnosis of COVID-19 to build the UMMC COVID-19 – Biobank collection.

**Methods:** This is an IRB approved research study to build the first Mississippi biobank of COVID-19 in adult and pediatric subjects. Biological samples and medical information are extracted from hospitalized SARS-CoV-2 patients in Epic. The invitation to participate in this research study is presented to patients who express interest to their treating physician who then request patient approval to be contacted by biobank research personnel. Informed consent is obtained either via eConsent through REDcap or a phone call service may be used to talk to the patients regarding obtaining the consent or if the patient is unable to make or communicate an informed decision due to mental or physical impairment, by talking to a legally authorized representative during the hospital admission. The consent process is followed with procedures to minimize exposure to SARS-CoV-2 for research personnel. Collection of blood samples occurs on day 1 after confirmed COVID positive test, and then subsequently on day 7, day 14 and day 21 in SST, EDTA, heparin PST and PAXGene DNA and PAXGene RNA tubes. All the blood samples are processed within 2 hours to create aliquots of serum, plasma, buffy coat, PBMCs and whole blood. Each biospecimen is labeled with a unique ID that is created by a biospecimen inventory software.

**Results:** Till date we have over 3,000 specimens from 300+ enrolled patients along with their clinical and biological data. We have disbursed about 120 specimens till now to UMCM and industry researchers. Each specimen request undergoes the review from biospecimen access committee in UMMC. This biobank collection is ongoing and we are continuously enrolling during the pandemic.

**Conclusions:** We expect to use these samples for future research including studies on the pathophysiology of COVID-19 such as diagnostic test validation, biomarker discovery, genomic testing, pilot projects, grant submissions in the adult and pediatric population. In addition, we plan to share these samples with the scientific community interested in advancing the knowledge on this disease.

**PB-04 Spaceflight Biospecimen Sharing in Support of Science Discovery and Exploration**

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For decades, NASA and international partners have flown non-human biological experiments in space to understand the effects of spaceflight and address potential biological hazards.
Sending organisms into space is a costly endeavor which makes space-flown biological specimens a valuable resource. To enable maximum scientific return, samples not required by the Principal Investigators are harvested and collected mostly by NASA’s Space Biology Biospecimen Sharing Program. These specimens are collected according to well-established SOPs that maintain quality and integrity. The specimens are then preserved, archived, and made available to the international scientific community through NASA’s Institutional Scientific Collection (ISC) at Ames Research Center (ARC). The ISC-ARC biospecimens and descriptive metadata are findable and accessible for request through the Life Sciences Data Archive (LSDA).

The NASA ISC-ARC currently stores over 32,000 specimens from Shuttle, International Space Station, and ground-based investigations (spaceflight analog experiments involving either hindlimb unloading, centrifugation, or partial weight-bearing study designs). Tissues are predominantly from mice and rats, though samples are also available from bacteria and quail. Tissues are stored at −80°C, −20°C, +4°C, or ambient and preserved in various fixatives. Historically, these tissues have been used for a wide range of analyses, including histology, genomics, and transcriptomics. Plans are underway to expand the ISC-ARC beyond the mostly-rodent contents, to include a space-relevant microbial culture collection including bacteria, fungi, and yeast. This expansion of the ISC-ARC will now involve identifying and standardizing best practices for microbial curations. To ensure safe long-term storage of microbial isolates, a microbiology laboratory will be dedicated for identification, cell culture, and lyophilization.

Awarding of tissue to public science investigators has resulted in 33 publications since 2011, with 48 requests being submitted since 2016. Of note, NASA GeneLab has been awarded ISC-ARC biospecimens in the past few years. GeneLab processes the biospecimens to generate various levels of ‘omics’ data, which are published on GeneLab’s open access online platform for bioinformatics analysis and visualization. This has helped a systems biology community grow around the ‘omics’ data, which are published on GeneLab’s open access online platform for bioinformatics analysis and visualization.

The specimen repositories have been involved in establishing strict collection and storage protocols for biological and environmental samples for 40 years. These standardized protocols are necessary to maintain sample and data integrity within not only an individual sample, but also when comparing samples collected across multiple years. Departures from a protocol can occur in the field due to limited staff, limited supplies, difficult weather conditions or other unforeseen circumstances. Such is the case in remote areas like the Alaskan coastline, where tissue samples are collected from deceased marine mammals as part of the National Oceanic and Atmospheric Administration’s (NOAA) Alaska Marine Mammal Tissue Archival Project (AMMTAP). Though protocol deviations are always noted, it is critical to understand the effects they have on specific downstream analyses. Here we present a case study using marine mammal tissues collected as part of the National Marine Mammal Tissue Bank (NMMTB) and archived at the NIST Biorepository located at the Hollings Marine Laboratory in Charleston, SC. Blubber, liver and kidney samples were collected from four deceased bottlenose dolphins (Tursiops truncatus) that stranded along the southeast coast of

Biodiversity/Environmental/Animal Repositories

PC-01 Genetic Assessment of Cattle in the Western Gauteng Region of South Africa

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Introduction: Gauteng, the smallest province in South Africa, has a large number of emerging or small-scale farmers contributing to the livestock sector. Western Gauteng in particular, is representative of large cattle populations, usually kept to generate household income and for traditional practices. These resources are often not well exploited and have potential to contribute to food security and conservation. Genetic analysis of livestock systems plays a crucial role in adaptation to a changing environment. The aim of this study was to determine the population structure and genetic differentiation among three cattle populations from Western Gauteng municipalities.

Methods: Hair samples from 266 cattle were collected from the three municipalities: City of Johannesburg (n = 108), Merafong (n = 87) and Randfontein (n = 71). Direct polymerase chain reaction (PCR) was conducted using eleven International Society for Animal Genetics (ISAG) standardised bovine microsatellite markers. Fragment analysis was done on a 3130XL Genetic Analyzer. Six local cattle breeds (Nguni, Brahman, Bonsmara, Angus, Drakensberger and Afrikaner) were included as reference populations. Statistical analysis was performed using MS Toolkit, STRUCTURE and GenAlEx programs.

Results: All microsatellite markers were highly polymorphic, with an overall polymorphic information content (PIC) of 0.779. A total of 142 alleles were detected, ranging from 8 (BM1824) to 21 (TGLA122), with an average number of 12.91 per locus. Expected heterozygosity values ranged from 0.729 (Merafong) to 0.790 (Randfontein) indicating high levels of variability in the study populations, with Randfontein having the highest mean number of alleles (MNA = 10.09). Levels of inbreeding within the populations varied from −0.031 to 0.042 with a mean of 0.018, illustrating low levels of inbreeding within the populations. A genetic distance of 0.103 was observed between Randfontein and City of Johannesburg populations and 0.248 between Merafong and City of Johannesburg. Fst values between populations were generally low, ranging from 0.016 to 0.038. Independent clustering of the three populations was observed although within each population a level of admixture was evident.

Conclusion: The results correspond to the information provided by farmers regarding the mating strategy employed. In addition, these findings may provide valuable information for the management of genetic resources and contribute to future breeding programmes.

Biospecimen Research and Science

PD-01 Using Non-targeted Metabolomics to Understand Protocol Deviation: A Case Study in Freezer/Thaw Effects

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The National Institute of Standards and Technology (NIST) has been involved in establishing strict collection and storage protocols for biological and environmental samples for 40 years. These standardized protocols are necessary to maintain sample and data integrity within not only an individual sample, but also when comparing samples collected across multiple years. Departures from a protocol can occur in the field due to limited staff, limited supplies, difficult weather conditions or other unforeseen circumstances. Such is the case in remote areas like the Alaskan coastline, where tissue samples are collected from deceased marine mammals as part of the National Oceanic and Atmospheric Administration’s (NOAA) Alaska Marine Mammal Tissue Archival Project (AMMTAP). Though protocol deviations are always noted, it is critical to understand the effects they have on specific downstream analyses. Here we present a case study using marine mammal tissues collected as part of the National Marine Mammal Tissue Bank (NMMTB) and archived at the NIST Biorepository located at the Hollings Marine Laboratory in Charleston, SC. Blubber, liver and kidney samples were collected from four deceased bottlenose dolphins (Tursiops truncatus) that stranded along the southeast coast of
the US. This species was chosen as a surrogate for Alaskan marine mammal species, from which protocol-adherent samples can be difficult to obtain. Each tissue was split into two samples; one was immediately processed and archived according to the standardized protocol while the other was processed using a common deviation protocol involving an additional freeze/thaw cycle prior to tissue processing and archival. After the final freezing in LN2 vapor-phase freezers (-150 °C), each tissue was cryohomogenized and divided into multiple fresh frozen aliquots. Non-targeted metabolomic analyses were performed using LC-HRMS/MS to compare metabolite profiles from samples prepared using the standard and modified procedures.

PD-02 Persistent Organic Pollutants in Bristol Bay Beluga Whales

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Remote high latitude locations are often sinks for persistent organic pollutants (POPs), which can ultimately bioaccumulate in local wildlife, such as beluga whales (Delphinapterus leucas). Of those inhabiting Alaskan waters, Bristol Bay belugas represent a healthy and stable population with ∼2000 individuals. Conversely, the Cook Inlet population has been in decline, and despite protective measures, is not recovering with ∼279 individuals remaining (Sheldon and Wade, 2019). To understand the decline of this sensitive population, health assessments of wild Bristol Bay belugas were conducted to obtain baseline parameters from a stable population from which to compare. This highly collaborative and substantial effort (e.g., federal and state agencies, aquariums, native associations) was conducted between 2008 and 2016. Of the samples collected, blubber and blood tissues were cryogenically archived at the National Institute of Standards and Technology’s Biorepository located at the Hollings Marine Laboratory in Charleston, South Carolina, USA, for retrospective analysis. Of those archived tissues, blubber from 50 beluga whales are being measured for POPs (e.g., polychlorinated biphenyls (PCBs), chlorinated pesticides (DDTs), polybrominated diphenyl ethers (PBDEs) and hexabromocyclododecane (HBCD)) and a portion of the preliminary data (i.e., PCBs, DDTs, oxychlordane, mirex and HCB) are presented here. To date, the total POP mass fraction for Bristol Bay beluga is 665 ng/g. In contrast, total POP mass fractions of these same compounds from blubber samples from Cook Inlet and the eastern Chukchi Sea, another geographically distinct beluga population, are reported at 2040 and 6550 ng/g, respectively (Hoguet et al., 2013). As such, POPs in Bristol Bay beluga are comparatively low lending to this population’s viability as a baseline population for future POPs measurements.

PD-03 PDX, Primary Cell Cultures, and Organoids, Oh My: The Exponential Demand for Well-annotated Avatars

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Background: The Duke University Health System (DUHS) BioRepository and Precision Pathology Center (BRPC) has procured thousands of human tissue samples which are then stored for future use and/or released to researchers across the United States. Released specimens are used in various ways such as for genomic research, biomarker research, or drug testing. More recently, there has been an increase in the requests for fresh/viable tissue samples to be used for creating patient-derived xenografts (PDX), primary cell-culture, and organoid models. These types of living models of cell populations are sometimes called ‘avatars’ and they must be generated from tissues that are recently procured and have not been frozen or fixed.

Methods: Investigators place requests with the BRPC for tissue samples to be used in avatar creation. Tissue samples that are to be used for PDX, cell-culture, and organoid generation are obtained from surgical and biopsy procedures. Samples are placed in specific media and released. The number of individual tissue samples procured and distributed fresh for PDX, primary cell culture and organoid model creation were recorded each year from 2012 through 2020.

Results: In 2012, 16 samples were obtained for PDX generation. In 2013, 178 samples were collected. The following year, 1 sample was released for primary tumor cell culture (PTCC) and 272 for PDX. The number of samples increased for both PTCC (12) and PDX (345) in 2015. Less were collected for PDX in 2016 but more were used for PTCC, 173. In 2017, 537 samples were obtained: 208 for PDX and 329 for PTCC. In 2018, a total of 652 samples were collected. With the addition of cryopreservation in 2019, a total of 621 samples were collected. In 2020, 405 samples were released to Duke researchers creating PDX models; 2 for PTCC; 403 for cryopreservation; and 17 samples were released to researchers outside of Duke that intend on using the samples for one of these purposes.

Conclusions: The total requests and successful collections of fresh tissue samples that are to be used for PDX, cell-culture, and organoid creation continues to increase since 2012. Cryopreservation of freshly procured specimens may allow for the creation of a “living biobank” to meet the demand for viable cells needed in avatar creation.

PD-04 Cryopreservation of Viable Human Tissues for Single Cell Sequencing: Comparison of Fresh tissue vs. Viably Frozen Tissues Dissociation Using QA Metrics Cell Viability

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Single cell sequencing is key to understanding the complex interactions between heterogeneous tumors and tumor microenvironment. Cryopreservation of tumor specimen and dissociated cells to support this effort is dependent on the viability and long-term storage. In a previous study, the Moores Cancer Center Biorepository established (1) that cryopreservation of
viably frozen tissue provided a renewable resource for development of PDX, cell lines, organoid, and improved RNA quality. Viable single cells are critical renewable resources for single-cell sequencing. This study seeks to determine whether dissociated single cells are a better modality for long-time preservation as compared to viably frozen tissue for single cell sequencing. We hypothesized that immediate cell dissociation prior to viable freezing will result in greater cell viability as compared to frozen tissue fragments although viable frozen fragments can serve as an alternative.

Human Tumor specimen were collected under Moores Cancer Center Biorepository IRB-approved protocol (181755). Tumor specimens were split into two groups for further analysis: viably frozen tissue (VFT) and viably frozen dissociated cells (VFDC). The Miltenyi Biotec gentleMACS Octo Dissociator was used to dissociate VFDC samples on the same day of collection and VFT samples a week later. The MOXI GO II cell counter was used to perform cell viability following dissociation and weekly freeze thaw cycles.

The data revealed that immediately dissociating and viably freezing cells resulted in significantly higher cell viability after up to three weekly freeze-thaw cycles. There was a significant difference between viability count VFDC and VFT samples one to three weeks after cell dissociation (p < 0.05). However, preliminary results also suggests that VFT is an option to dissociate cells for single cell sequencing. This finding suggests that biobanks should consider cryopreserving dissociated tumor cells to maintain superior quality for future use. Cryopreservation of tumor fragments can be an alternative when immediate cell dissociation is not possible. We plan to compare downstream single cell sequencing for both cohorts.

PD-05 DNA Quality, Quantity and Sequencing Reads of Breast Cancer Tissues Stored in Research Biobank, FMUI - dr. Cipto Mangunkusumo National Central General Hospital

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Introduction: In this post-genomic era, the sequencing needs arise rapidly, produce huge genomic data. Analysis of such data has the potential to support various research and applications, including genomic profiling for personalized medicine, drug and vaccine discovery. To supporting genomic research, FMUI – dr. Cipto Mangunkusumo National Central General Hospital is supported by the Biobank Research facility which plays a role in storing biological samples from various patients supplemented with clinical and pathological data. One of the biological samples stored in the biobank is a sample in the form of fresh frozen tissue carried out in a freezer –80°C. A critical component of a biobank facility is the ability to store high-quality samples for long periods of time. The aim of this study was to analyze the impact of storage in Biobank Research facility on the quality and purity of DNA and the quality of its sequencing reads.

Method: This study used 24 fresh frozen breast cancer tissue samples stored from 2014, 2015, 2016, and 2017. All samples were stored in –80°C storage of Research Biobank FMUI - dr. Cipto Mangunkusumo National Central General Hospital. DNA purity quantification for samples was performed using NanoDrop and Qubit4. Sequencing was done for 24 samples by using Ampliseq for cancer hotspot panel protocol in MiSeq (Next Generation Sequencing machine).

Result: From ANOVA statistical regression tests, it is known that there is no significant difference between the DNA concentrations obtained from the 2014-2017 samples (p=0.237). The results of statistical tests showed there’s no significant difference between DNA purity of the samples stored from 2014-2017 (p=0.111). These non-significant results also impact the sequencing results using the MiSeq Next Generation Sequencing machine using amplicon cancer hotspot genes panel, which showed that the percentage of sequencing reads of samples stored in 2014-2017 also has no significant difference (P=0.131).

Conclusion: These non-significant difference results shown that sample storage in –80°C freezer in Biobank Research Facility remains a viable option for maintaining the quality of tissue in Biobank.

PD-06 Dried Blood Spot (DBS) Collection for SARS-CoV-2 Antibodies


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Background: The COVID-19 antibody sub-study of the Canadian Longitudinal Study on Aging (CLSA) has been designed to examine the seroprevalence of the SARS-CoV-2 infection from 19,000 participants across Canada over three time periods. The largest set will be performed by in-home collection using a dried blood spot (DBS) device.

Methods: We evaluated two self-collection devices, Mitra® (Neoteryx) and Velvet™ (Boston Microfluidics), considering cost, delivery, availability, ease of sample collection and return, sample volume, blood fractionation, normalisation requirement, hemolysis, and analysis of additional analytes and ease of storage. We developed collection instructions, a quality of collection questionnaire, and a process to ship, return and store the devices.

Results: Velvet™ was selected for several reasons. Hand eye coordination was less demanding for collecting drops of blood into a well compared to dropping blood on several microfiber tips for the Mitra®. Normalization for volume collected is needed for both, but hemoglobin interference is not an issue with Velvet™ as blood is fractionated into cell components and plasma. Storage of Velvet™ at –80°C was easier than Mitra® with a unique barcode on each device for scanning and were easily stackable in trays with its rectangular shape and smooth surface. Customized collection kits were made with devices, retractable lancets, gauze, Band-Aids, return pouch and in-
PD-07  Infinity Biologix – A Global Stem Cell Resource

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Since its inception in 1998, RUCDR Infinite Biologics has provided the global scientific community with the highest quality biomaterials, technical consultation, and logistical support. In 2011, with rising interest in induced pluripotent stem cells (iPSC) models of human development and disease progression and for drug screening and toxicology testing RUCDR began offering a wide range of stem cell services. These include source cell and iPSC banking, iPSC generation, iPSC gene editing and source cell and iPSC distribution. On August 17th, 2020, Rutgers University completed the sale of RUCDR and Infinity Biologix was created. As Infinity Biologix, we have the same core mission, advancing research globally. Infinity Biologix maintains the multiple NIH stem cell repositories including the NINDS Cell and Human Data Repository (NHCDR) (https://bioq.ninds.genetics.org/) and the NIMH Repository & Genomics Resource (https://www.nimhgenetics.org/). These repositories house iPSC, fibroblasts and cryopreserved lymphocytes from more than 1000 subjects, including a GMP grade iPSC cell line. These cell lines are available to academic and for-profit researchers worldwide.

All iPSC generated and distributed by IBX include the following minimum set of QC assays - sterility (including mycoplasma), identity, expression of the stemness marker alkaline phosphatase, and expression of the stemness markers Oct4 and Tra-1-60. In addition to these assays, many cell lines have been karyotyped, been shown to have lost the expression of the reprogramming factors and have been assayed for differentiation into all 3 germ layers. All cell lines are available to academic and for-profit researchers worldwide.

Commercial Biobanking

PL-01  Regional Biobanking Industry Alliance Drives Market Development

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There are abundant human genetic resources in China, but the relevant biobanking industrial connections are still not perfect. Here, we put forward a strategy for constructing the “Regional Human Genetic Resources Industry Technology Strategic Alliance (R-HGRITSA),” which focuses on improving the utilization of resources and meeting the needs of bio-
banking associated industry development. For such alliances, universities are the driving force of innovation, hospitals are the source of biospecimens, and business enterprises are the carriers of operations. Within the alliance, the standardized construction of a human genetic biobank was introduced, and guided in more detail by holding academic and training conferences. Depending on the needs of hospitals, scientific research institutions and enterprises of different sizes in the region, big data resources using the best practices of distributed biobanks were provided to help biobanks’ construction in accordance with local conditions. The strong collaboration among the alliance members will drive the comprehensive development of related enterprises. For example, cold chain enterprises will focus on breakthroughs in cryopreservation technology and accelerate the research and development of automation technology products. Hospitals and third-party inspection institutions will actively explore the feasibility and practicality of building standardized biobanks according to their own development planning and conditions. Biomedical enterprises with demands for applications for human genetic resources, such as antibody research and development, stem cell/immune cell preparation, targeted drug development, and diagnostic reagent research and development, can be based on the conditions of existing traditional biobanks or living biobanks in the region. The types of services that can be provided will be adjusted to the businesses’ direction and scale. Consequently, the upstream and downstream enterprises related to the biobanking will be united to establish a complete innovation chain of production and scientific research. The enterprises’ core competitiveness will be enhanced by genetic resources.

Ethical, Legal, and Social Issues

PE-01 The Implementation of Singapore’s Human Biomedical Research Act (HBRA) Human Tissue (HT) Framework in an Academic Institution Setting to Regulate Tissue Banks and Tissue Banking Activities for Research

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Singapore’s Human Biomedical Research Act (HBRA) defines the roles and responsibilities of individuals and institutions involved in human biomedical research and the handling of human tissue for use in research to protect the safety and welfare of research subjects and tissue donors. The human tissue (HT) framework of HBRA, activated on 1 November 2019, include provisions to regulate tissue banks and tissue banking activities for research. Here we described the implementation of a single mothership model for HT framework in an academic institution (National University Health System, NUHS) for reporting biobanking activities to the Ministry of Health Singapore. This involves harmonizing policies, procedure and auditing of satellites biobanks prior to the annual submission.

PE-02 The Importance of Understanding Regulations Governing the Use and Transfer of Biospecimens

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Statement of the Problem: Regulations governing the sharing of biospecimens can be challenging to navigate. Some regulations, such as the need for shipping permits, stem from safety concerns. Others, including stipulations in Material Transfer Agreements (MTA), arise from legal contracts.

Import/export/interstate transport permits may be needed for some but not all of a biorepository’s specimens. Understanding shipping permit requirements is time consuming, involving thorough research through multiple sources of information. In the United States, the following governmental agencies regulate the transport of biological material:

- Department of Agriculture – Animal and Plant Health Inspection Service (APHIS)
- Centers for Disease Control (CDC)
- US Fish and Wildlife Service (USFWS) for oversight of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

The permit application/review process can take several weeks to complete. It is therefore incumbent on biorepositories to understand the regulations and obtain necessary permits in advance of shipping timelines to avoid delivery delays that could jeopardize sample integrity and project timelines.

Restricted on biospecimen use are also documented in MTAs or other contracts; however, that information is not always transparent to the staff who handle the specimens. Transferring such regulated specimens without additional approvals would constitute a breach of contract.

Proposed Solution: Biorepository managers should be proactive in understanding and documenting the regulations and contracts that apply to their repository’s specimens, storing pertinent information in a central location easily accessed by all team members. Shipping permits should be obtained to cover the predictable specimen shipment requests. In addition, biorepository staff members should be trained to check for requirements and restrictions when the shipment or transfer request is received to ensure compliance.

Conclusions: Failure to apply for and receive all applicable permits before shipping biological specimens can result in customs delays, fines or worse. Similarly, transferring or using samples without proper permissions can lead to legal challenges. Biorepository staff must be familiar with all associated shipping regulations and associated contracts; accordingly, biorepositories should prepare complete documentation their unique requirements and fully train staff to ensure regulatory compliance.

PE-04 Knowledge, Perceptions and Attitude of Egyptian Physicians towards Biobanking Issues


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Background: Collection and storage of biospecimens and data for biobanking raise many ethical concerns. Stakeholders’ opinions about these ethical issues are important since they can
help in the development of ethical guidelines to govern biobanking activities. Physicians are among the important stakeholders since they contact potential participants and could be biobank users. The goal of this study is to evaluate the perceptions and attitude of Egyptian physicians towards ethical issues in biobanking.

**Methods:** A cross-sectional online survey was designed and communicated with the target group between November 2019 and January 2020.

**Results:** The questionnaire was completed by 223 physicians. While 65.5% reported hearing the term “Biobanking” before, 45.7% knew that there are biobanks in Egypt. Participants had a general positive attitude towards the value of biobanks in research. About 73% agreed that biobanks can share samples with international research organizations, but only 42.6% supported collaboration with pharmaceutical companies, and 44% agreed to the use of user fees by biobanks. About 48% supported the use of broad consent in biobanks, and 73.1% believed that sample donors should be informed about results of research performed on their samples.

**Conclusions:** Although many Egyptian physicians heard about biobanking, they had limited knowledge about the existence of biobanks in Egypt. They had concerns about commercialization, use of broad consent and user fees. A knowledge gap exists among these stakeholders, which should be covered by different educational activities. Community discussions should start to reach consensus about the issues of commercialization and return of research results.

**Hot Topics**

**PF-01** The Impact of a Research Resource: A Two-Year Review of Peer-Reviewed Publications Utilizing Samples from the NIGMS Human Genetic Cell Repository

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**Background:** The NIGMS Human Genetic Cell Repository (HGCR) is a biobank hosted at the Coriell Institute for Medical Research that stores, processes, and distributes cell lines and DNA samples to researchers around the world. The HGCR collection currently comprises more than 11,700 fibroblast and lymphoblastoid cell lines, over 6,300 DNA samples, and 64 induced pluripotent stem cell lines, derived from individuals with heritable diseases or chromosomal abnormalities, apparently healthy controls, and geographically diverse populations. These well-characterized biospecimens are used regularly by investigators studying cell biology, genomics, bioinformatics, and bioengineering, and is an essential resource for high-quality and reproducible research.

**Methods:** In order to better understand the specific uses of these specimens, we surveyed the peer-reviewed literature that cited the use of samples from the HGCR in studies published during 2019 and 2020. Publications were identified for review by keyword search from the Google Scholar index and filtered for inclusion based on an explicit citation of a Repository ID. Publication metadata that was analyzed was gathered from the article text, article keywords, and the content of the abstract.

**Results:** Over 650 publications were identified, referencing cell lines or DNA samples from the Repository more than 4,000 times. These publications originated from laboratories worldwide, representing both the academic and commercial sectors, and included research applications that ranged from technological improvements to basic science investigations. In-depth analysis of the research topics central to each publication revealed the scientific fields which are most studied using HGCR samples, providing insights into the ultimate applications of this Repository’s resources.

**Conclusion:** Over time, these analyses will serve to highlight evolving trends in research that utilize NIGMS HGCR samples. Interpretation of the research trends offers a mechanism for feedback to highlight the effective range of use of the biomaterials provided by the HGCR. Understanding the research impact of its samples provides an opportunity to improve the HGCR and the diversity of samples in the collection with the aim of promoting impactful research and stimulating the advancement of scientific knowledge.

**PF-03** Driving Innovation and Discovery Through Collaboration to Address Global Challenges at UHN Biospecimen Services

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UHN Biospecimen Services, University Health Network, Toronto, Ontario, Canada

**Background:** Biobanks are crucial in the understanding of COVID-19 risk factors, mechanisms of infection, and for the development of vaccines and potential treatments. By providing high-quality biospecimens and associated clinical data, biobanks enable researchers to combat the existing global crisis as well as prevent future outbreaks.

**Methods:** In response to the COVID-19 pandemic, UHN Biospecimen Services assembled a collaborative task force comprised of clinicians, biobank experts in biospecimen management and regulatory compliance, quality assurance, technology, pathology, infectious diseases, and clinical research. With this highly skilled group of experts, UHN Biospecimen Services helped build and support a specialized biorepository for all COVID-19 related research initiatives across University Health Network (UHN). Intricate inter-departmental and inter-institutional collaborations, complex logistics and versatility from multiple parties were crucial in the process of bringing this initiative to life.

**Results:** A collaborative, centralized biorepository was developed, storing high-quality biospecimens from participants presenting with upper respiratory and COVID-19-like symptoms. Biospecimens have been collected from over 400 participants consented to the UHN COVID-19 Biobank since May 2020. Currently, over 18,000 derivatives from serialized collections are available for analyses, including: blood components, nasal swabs, urine and saliva.

**Discussion:** By connecting and collaborating through biobanking, the UHN Biospecimen Services provides researchers and clinicians with essential resources that can be employed to better understand the virus’ dynamics and develop effective life-saving countermeasures.

We have adopted a holistic approach to research on COVID-19 to support research interests in various cohorts and hope to continue to build this collaborative network and biorepository to fuel innovation and discovery and support research to fight and address emerging global health challenges.
**Human Specimen Repositories**

**PG-01 The timely involvement of Biobank Pilsen (Czech Republic) in the COVID-19 Pandemic**

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Background: The pandemic of COVID-19 affected all health care systems worldwide and the Czech Republic was one of successful European countries during the first wave in early spring 2020. The epidemiological data of COVID-19 deaths were compared with influenza deaths data from 2018, 2019 significantly lower. Currently the Czech Republic is facing the second wave with much worse course than in spring 2020.

Methods and Results: University Hospital in Pilsen is the key health-care institution in the region and the pandemic completely changed the functioning of the whole hospital. Laboratory of immunochemical diagnostics and Biobank were among the departments which have flexibly responded to the novel situation. While clinical departments were put into the emergency regime, the laboratory and Biobank started specimen collections related to COVID-19 and probing of antibody and later on antigen tests from different manufacturers.

Samples related to COVID-19 (blood plasma and serum) as well as associated data have been collected, according to standard biobank collecting procedures, and were used partially for internal research purposes. From March to May, all blood sample leftovers of the diagnostics routine were stored in biobank as -Population samples COVID-19- group (approx. 3.800 specimens). From June two sample collections were organized: 1/ University Hospital employees (approx. 1500 subjects), 2/ COVID-19 positive subjects – samples collected 4 weeks after the healing. Antibodies Anti-SARS-CoV-2 and 25OH vitamin D were measured in these samples and repeated tests on these subjects are planned after 3 and 6 months.

Conclusions: University Hospital in Pilsen responded to the COVID-19 pandemic very quickly, effectively, and flexibly, to save the health of COVID-19 patients, and medical staff at all levels, and contributed to the successful controlling of pandemic. Biobank in Pilsen started specimen collections related to COVID-19 for probing of antibody and later on antigen tests, and for future research.

COVID-19 related activities were coordinated at national level and at the international level with BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium).

The study was supported by the Ministry of education, youth and sports LM2018125, CZ.02.1.01/0.0/0.0/18_046/0015959.

**PG-02 Fast-Tracking a COVID-19 Biospecimen Resource in Response to the Pandemic**

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1Biobank Core Facility, Saint Joseph’s Hospital and Medical Center, Phoenix, Arizona, United States, 2Saint Joseph’s Hospital and Medical Center, Phoenix, Arizona, United States, 3Chandler Regional Medical Center, Chandler, Arizona, United States

Background: Healthcare Workers (HCWs) are at particular risk for COVID-19 since they are in frequent and direct contact with known and suspected COVID-19-positive patients. Appropriate measures and proper PPE are being used in healthcare facilities worldwide to prevent COVID-19 exposure to HCWs however data from around the world suggest that HCWs are infected at a higher rate than the general population. Monitoring possible exposures of HCWs through changes in seroprevalence over time is critical to understanding more of the spread of the virus and how to better support HCWs during the pandemic. In addition, creating a COVID-19 biorepository would be a critical tool in facilitation of much-needed COVID-related research.

Methods: To fast-track the COVID-19 biorepository, participants were limited to HCWs from six hospitals and care facilities in Maricopa County, AZ, and were active members of the healthcare or medical staff during the pandemic at the time of enrollment. Data collection included demographics data and self-reported medical histories and symptoms.

To encourage HCW participation and facilitate enrollment, an online consent was created so that HCWs could consent and complete the Perceived Wellness Surveys. After consent, participants were routed for diagnostic testing utilizing the Abbott ARCHITECT SARS-CoV-2 IgG assay and had two tubes of blood collected for biobanking, storing up to 5 aliquots each of serum and plasma. For every participant, sample and survey collections would occur every three months for a one year period.

Results: Biospecimen collection for biobanking began in June 2020 and to date, more than 24,000 plasma and serum aliquots from over 1200 participants have been processed and stored in the Biobank Core Facility (BCF). The participants range from 20 to 60+ years of age and represent a diverse racial/ethnicity population. At baseline, the positivity rate for COVID-19 exposure from this cohort was approximately 9.4% and 3 months later was approximately 11.5%.

Conclusions: During COVID-19, our BCF serves as a valuable resource to our facility’s response to the pandemic by providing an infrastructure for specimen collection as well as specimen storage/dispersal to COVID-related research. Biobanked specimens are currently supporting several COVID research initiatives ranging from a pilot study looking at antigen specific cellular immune responses to another project focused on developing high sensitivity/high specificity serological assays.

**PG-03 Researchers Increasingly Request Custom Fresh Tissue Samples From CHTN MWD Over Conventionally Biobanked Frozen and Fixed Tissues**

D. G. Nohle, R. Mandt, M. E. Couce, L. W. Ayers, A. Parwani

CHTN-MW Division, Columbus, Ohio, United States

Background: Cooperative Human Tissue Network (CHTN) Midwestern Division (MWD) is a National Cancer Institute funded program to provide quality research biospecimens to qualified investigators. Unlike most biobanks, tissues can be procured fresh and shipped in investigator specified and provided media. The OSU Research Tissue Procurement – Information System (RTP-IS) is used to manage data related to biospecimen procurement, shipping and billing for processing fees.

We previously noted an increase in custom fresh research tissue requests at a time when frozen tissue requests declined and wondered whether this trend continued beyond 2018.

**ABSTRACTS**

**PG-02 Fast-Tracking a COVID-19 Biospecimen Resource in Response to the Pandemic**

R. Singh1, J. Cogo2, C. Elliott1, B. Tiffany3, J. Eschbacher2

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We previously noted an increase in custom fresh research tissue requests at a time when frozen tissue requests declined and wondered whether this trend continued beyond 2018.
Methods: RTP-IS was used to produce statistics about biospecimen preparation type and media. Tissue preparation types were reviewed from 2015 - 2019 for fresh, custom fresh, standard fresh in CHTN provided media, frozen and fixed sample types.

Results: Over the time period reviewed, the investigator requested custom fresh samples distributed rose from 954 samples (11.3% of total shipped) in 2015 to 1,230 or 22.5% in 2019. In contrast the number of fresh tissue samples distributed in standard CHTN media remained stable but the % of these fresh-standard media samples rose from 10.2% to 28.8% due to fewer requests for frozen and fixed samples. Distributed frozen samples declined from 4,387 in 2015 to 569 in 2019 with the % declining from 51.8% to only 10.4%. Distributed fixed samples also showed a change from 2,267 (26.8%) to 2,099 (38.3%). The % of samples shipped to academic investigators decreased while the % to commercial investigators increased over the period. As of 2019, the % shipped to commercial investigators outstriped that shipped to academic and government combined.

Distribution of fresh tissue is increasingly important (ranging to 51.3% in 2019) and is now more commonly provided than Fixed (38.3%) and Frozen (10.4%) combined. In 2019, Fresh was divided between Custom (22.5%) and those specifying one of several Standard options (28.8%).

Conclusions: The CHTN MWD has adapted procurement to accommodate researcher requests for fresh tissue with the use of custom media provided by the researchers. Some of this change reflects a change in the mix of academic and commercial investigator types served by the CHTN MWD but also reflects the type of research being performed. This continuing trend portends poorly for conventional fixed and frozen tissue Biobanks. We must continue to follow and adapt to the needs of the research community.

PG-04 Purpose-built Lung Explant Biobanking: Not All Explants are Created Equal
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Background: In order to address research interest of lung explant tissue, the Duke University Health System (DUHS) BioRepository and Precision Pathology Center (BRPC) has worked alongside the lung transplant team at Duke University Hospitals to consent patients to the bio-banking protocol. Once patients are consented, the transplant team coordinates with BRPC to process tissue for researchers at Duke and UNC. BRPC has facilitated research tissue collections for Cystic Fibrosis (CF), Idiopathic Pulmonary Fibrosis (IPF), Bronchiolitis Obliterans Syndrome (BOS), Chronic Obstructive Pulmonary Disease (COPD), Interstitial Lung Disease (ILD), Sarcoidosis, and Pulmonary Hypertension (PHTN).

Methods: Lung explant specimens were collected and processed per BRPC’s standard operating procedure. Samples were released fresh to investigators and/or stored long term in FFPE and OCT. Data were analyzed retrospectively from 2013 to 2020 to investigate the variety of lung transplant cases BRPC facilitates and potential research preferences for diagnosis types. Diagnosis data of lung transplant recipients from the U.S. Department of Health and Human Services was pulled for a similar interval of 2013 to 2020 to compare population trends.

Results: From 2013 to 2020, BRPC has facilitated 162 total lung transplant tissue encounters, yielding 5077 total samples. The breakdown of disease types is as follows: 59 CF (36.42%), 56 IPF (34.57%), 34 BOS (20.99%), 5 COPD (3.09%), 3 ILD (1.85%), 3 Sarcoidosis (1.85%), and 2 PHTN (1.23%). According to data from the U.S. Department of Health and Human Services, from 2013 to 2020 there have been 18,074 transplants nationally, of which were 10.04% CF, 34.55% IPF, 19.88% COPD, and 2.64% PHTN. BOS, ILD, and Sarcoidosis were not specifically reported on, but may fall into the Other Lung Disease category (22.42%).

Conclusions: Research interest of different lung explant types for bio-banking at BRPC can be examined by differences in research collections from population trends. Of note, a greater percentage of lung transplant research cases occurred for cystic fibrosis than what would be estimated from the population statistics. COPD in contrast had far fewer research collection encounters despite making up almost 20% of the lung transplant diagnoses for the years 2013 to 2020. BOS lung transplant tissue, which was not specifically reported on by the U.S. Department of Health and Human Services, also made up a large component of research tissue collections.

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Diagnosis of haematological cancer requires the involvement of high-technical methods with high sensitivities and specificities. Flow cytometry (FCM) is a technique which allows rapid and dynamic analysis of single-cell and can be combined with cell sorting. In the last 3 decades, the utility of FCM has expanded to investigate the antigens present on normal and malignant cells.

Proposed Solution: In Vietnam, the application of this technique remains limited, ranging only in leukemia and myeloma. In most of the laboratories, diagnosis of haematological cancer is mainly based on immunohistochemistry, complete blood count, bone marrow biopsy & aspiration. Thus, the result of examination is depended on haematologist and sometime, is lacking of objectivity. This classical method is only effective in situations in which the signals are apparently clear.

The increasing of new cases diagnosed with haematological cancer in Vietnam raised the suggestion of a novel, dynamic method and FCM are considered applying in near future. Vietnam National Cancer Hospital did release a proposal of progressing FCM, aims to accurately diagnose and identify types of blood cancer.

For leukaemia, we are planning combined tests of 19 markers, including CD4, CD5, CD8, CD20, CD23, CD25, CD26, TCRγδ, TCRαβ, etc. Based on the expression of these markers, we can distinguish the diagnosis as T cell neoplasms including T cell prolymphocytic leukaemia (T-PLL), large granular lymphocyte leukaemia (LGL), Sezary syndrome (SS); or B cell neoplasms including chronic lymphocytic leukaemia (CLL), hairy cell leukaemia (HCL), mantle cell lymphoma (MCL) and follicular lymphoma (FL).

For myeloma, we are making a protocol for combined tests, including CD38, CD138, CD56, CD117, CD52, CD19 and CD45, to distinguish distinct populations of plasma cells.
Besides, protocols for application of FCM in diagnosis of lymphoma are on process of standardization and are promising to be utilised.

We are preparing Navios EX Flow Cytometer to be set and cooperating with French Saint Louis Hospital for training this new technique.

Conclusion: FCM is a potential standardized method for diagnosis of haematological cancers in Vietnam. Comprehensive preparation should be carried out to reinforce the accuracy of disease diagnosis.

PG-06 Biobanking in Pakistan: 2 Years’ Experience at Shaukat Khanum Memorial Cancer Hospital & Research Centre

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Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore, Punjab, Pakistan

Background: Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) is a charitable, not-for-profit institution, whose mission is to provide the best possible cancer care to all its patients, irrespective of their ability to pay. During the last twenty-six years, 191,389 patients were registered at SKMCH&RC. Therefore, a considerable amount of various cancer tissues can be acquired and preserved. We have recently developed the bio bank facility of fresh frozen samples.

Methods: Research personnel and clinicians coordinate to acquire, store, characterize and catalogue the samples obtained from surgical resections of treatment naïve patients. The patients are scrutinized and consented for participation in bio banking. Tumour tissues obtained are snap frozen in liquid nitrogen and stored at −80°C. We have adapted the standard operating procedures (SOPs) developed by Canadian Tissue Repository Network (CTRNet), based on structural and organizational resources available at SKMCH&RC. The Institutional Review Board (IRB) of the SKMCH&RC has approved the current project.

Results: Since February 2019, we have enrolled 398 cancer patients. Currently, biobank contains about 311 frozen samples. These include breast 174 (55.94%), colorectal 98 (31.51%), head & neck 28 (9.0%), gastrointestinal 08 (2.57%) and sarcoma 03 (0.96%). Recently, new sites (Ovarian cancers, Hodgkin’s lymphoma and non-Hodgkin’s lymphoma, Pancreatic malignancies and Hepatocellular carcinomas) have been added and further expansion is still ongoing.

Conclusion: Biobank will support research projects to analyze diagnostic, prognostic and therapeutic targets for cancer patients. It will enable us to develop international research collaborations. The research data might play an important role in advancement of therapeutic modalities and management of cancer in a global perspective.

PG-06 The Human Exposome Assessment Platform (HEAP)

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Introduction: Over the last two decades there has been an enormous advancement in understanding environmental exposures and their biologic effects. The sum of all these biological exposures and their subsequent effects have been collectively termed the ‘Exposome’. Exposome research can result in the design of cost-effective health interventions targeting environmental risk factors that affect human health. For instance, it is clear that the age-adjusted incidence of chronic diseases such as cancer, is rising. The exposome risk factors behind this increment are not fully determined. An integrated research framework that efficiently provides a streamlined platform will dramatically contribute to identifying the environmental factors affecting human health. This can be achieved through exploiting major technologies and disciplines, collected samples and data from biobanks as well as prospectively collected population cohort samples and data.

HEAP (https://heap-exposome.eu/) is an EU-funded project that aims to provide a system for obtaining, managing, sharing and analysing exposome data. Large-scale, comprehensive and population-based information will be exploited to build sustainable systems for measuring the human exposome and its impact on health. Furthermore, innovative wearable exposure sensors will monitor exposures to pregnant women in relation to healthy childbearing. The poster displays the central role of biobanks to the exposome research as part of the pioneering EU-funded project.

PG-08 The Effect of Storage Period on DNA Quality of Fresh Frozen Cancerous Tissue Stored at −80°C at Research Biobank FMUI-Cipto Mangunkusumo Hospital Indonesia

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Introduction: The Global Cancer Observatory 2018 database showed a significant increase of cancer cases in Indonesia. Research on cancer leads to molecular study which requires DNA material. One of the factors which affected the DNA quality is the storage period of the biospecimen. Some experiments demonstrated that there is a connection between storage period of the cancer tissues with the DNA quality. Research Biobank Faculty of Medicine Universitas Indonesia (FMUI) - Cipto Mangunkusumo Hospital as biorepository needs to assure the quality of the stored biospecimen; therefore, it can produce good quality genetic materials which can ensure a research validity. The objective of this study was to analyze the DNA quality on fresh cancerous tissues (assessed by three indicators: purity, concentration, and fragmentation) which stored in −80°C on above and below two years.

Method: The study used 50 samples of cancerous tissues which divided into 2 groups that were stored in −80°C. The 1st group was the samples which stored above the 2 years’ time; the 2nd group was stored less than 2 years period. Quality test was run on DNA resulted from extraction of cancer tissues which performed with nanodrop 2000 absorbance ratio 260/280 nm for purity and 260 and 320 nm absorbance for total DNA concentration. Qubit Fluorometer 2.0 was utilized for obtaining integrity DNA concentration. Agarose gel electrophoresis was taken to observe the existence of DNA fragmentation. The data was analyzed using Mann-Whitney and Chi-Square.
Result: There is no significant difference of DNA purity (median 1.95 (1.68 - 2.17) vs (median 1.96 (1.85 - 1.98), p=0.96), integrity DNA concentration (median 101.5 (3.24 - 500) vs (median 202(7.67 - 370), p=0.145) and DNA fragmentation (38% vs 25%, p=0.055) between sample which stored above 2 years (n=20) and which stored less than two years (n=30). In contrast, the total DNA concentration is significantly higher on samples which stored less than 2 years (median 100.2 vs 271.9, p=0.025).

Conclusion: The storage period of fresh cancerous tissues above 2 years at −80°C does not have an impact on DNA purity, integrity DNA concentration and DNA fragmentation level. However, the storage period above the 2 years will influence total DNA concentration. In order to preserve the high quality of specimens in biobanks, extended cryogenic storage after 2–11 years remains a viable choice.

Keyword: Cancerous tissues, DNA, storage period, temperature of −80°C

PG-09 Adjustment to COVID-19 Era: Ongoing Process at Biobank at Faculty of Medicine, Public Health and Nursing UGM (FKKMK UGM), Yogyakarta-Indonesia

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Biobank at FKKMK UGM has just established for 2 years, when COVID-19 pandemic hit. Initially FKKMK UGM Biobank focused its service to non infectious related biosamples, due to limited infrastructure and expertise. On the first three months of COVID-19 pandemic, biobank was shut down. As the pandemic is expected to last longer, biobank must resume its operation. Adjustment is needed for this facility to enable it to cover service for “potential infectious” biosamples.

To achieve the objective, based on current capacity, several activities are needed to be done, included; 1. Identification of potential needs and risks; 2. Preparation for capacity building; 3. System adjustment. These activities are planned to be finalized by mid 2021, while the faculty experiencing financial constriction.

With the guidance from institutional biosafety team, by the end of 2020, Biobank FKKMK UGM determined that samples in virus-transfer medium (VTM) are prohibited, while already-prepared frozen COVID-19 related blood samples can be stored in biobank. We determine 3-layers packing system for biosamples entering biobank, and train our user to adhere. A home-made disinfecting chamber is in place to automatically clean the surface of outer biosample packing. Processing laboratory is disinfected regularly with ultraviolet light, and all technician wear adequate personal protection equipment (PPE) while working. Biosamples process is done in biosafety class II chamber, and biosamples are processed carefully to avoid vapour and spill-out.

Despite the adjustment, adequate and formal training in handling this highly infectious biosamples is still needed. While SARS-CoV2 infection soaring, vaccination program among laboratory personnel becomes paramount. Collaboration between biobank and facility equipped with negative pressure processing laboratory needs to be initialized; however, at present, this facility is being used to support COVID-19 diagnostic laboratory in the campus.

PG-10 Implementing a Multi-Stakeholder Approach in an Effort to Prioritize Rare Diseases in South Africa: Concept Design

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Statement of the Problem: Rare diseases (RD) are currently not a priority in South Africa (SA) and gaining support from the public sector and recruitment of participants has proven challenging. Problems experienced to date include: lack of support from government and limited expertise of clinicians; lack of knowledge on RD; limited access to diagnostic and genetic services; public health care focus not inclusive of RD; patients not returning for follow-up visits; and unwillingness to participate due to fear of exploitation and stigmatization. The North-West University’s (NWU) Centre for Human Metabolomics (CHM) has recently established the first RD biobank in SA and Africa, with recruitment currently under way. The need for such a biobank was identified by the CHM diagnostic laboratory through the number of patients that get diagnosed with a rare inborn error of metabolism.

Proposed Solution: A recent publication in Nature Genetics listed potential resources, based on international models that could be utilized to drive action towards the prioritization of RD in Africa. The aim of this study is to determine through application to what extent these resources (e.g. continental and international networking, international partnerships and wider collaborations in research and diagnostics for rare diseases) are actually accessible and achievable for an individual organization such as the CHM Biobank and to measure the effectiveness in bridging the challenges experienced to date in SA. The CHM Biobank will aim to work together with multiple stakeholders in the field of RD to set up and test an effective model for research collaboration and present an evidenced based case to SA policy makers to leverage support.

Conclusions: There is a great need for action towards prioritizing RD on the African continent. The needs of RD patients are often overlooked in comparison to the provision of basic needs (such as nutrition) and efforts aimed towards the prevention and treatment of communicable diseases. In order for SA to achieve
the United Nations Sustainability Development Goal (SDG) 3 targets, “ensuring good health and well-being for all ages at all stages”, RD patients can no longer be left behind. It is of the utmost importance to rethink standard practices in setting up RD infrastructure, including biobanks and networks in lower-middle income countries to overcome the barriers listed above.

PG-11 Perception of Biobanking among Sample Collectors, Sample Transporters, Laboratory Staff and Biobank Staff at Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit

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Background: Involving participants and stakeholders in biobank research activities is currently at a high demand. There has been research carried out to explore the views towards biobanking among researchers, participants, REC (Research Ethics Committee) members and patients. However, there has not been much research that has been done to explore views of professionals in the biobanking field. The aim of this study was to understand the level of knowledge of biobanking and the perceptions towards biobanking.

Methods: This cross-sectional study used a qualitative research methodology to explore the perceptions and the level of knowledge towards biobanking among sample collectors, sample transporters, laboratory staff and biobank staff at Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit. An in-depth interview guide was used to collect the information, and all interviews were audio recorded.

Results: A total of 17 participants took part in this study. Several participants (70.6%) associated biobanking to the storage of samples for future use and research purposes. 82.4% participants also linked a biobank to a facility that deals with handling of samples and has different storage equipment and controlled temperature conditions. Participants felt that more biobanks were needed in Uganda. 76.5% were also willing to donate samples and 52.9% supported shipping of samples out of Uganda.

Conclusion: Despite their knowledge about biobanks, there seemed to be a gap in the awareness of all biobanking activities. Although many recommendations were suggested, one important aspect to take from all that would be that the biobanks should be transparent about the activities they carry out and what guidelines they follow. Understanding the concerns raised by the respondents and putting them into consideration can help improve on biobanking in Uganda and at Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit.

PG-12 Recent Activities of Korea Gynecologic Cancer Bank

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Background: Human-derived specimens emerged as important resources for basic and transitional research in gynecologic cancer which is critical in accelerating development of molecular-based diagnostics and therapeutics for precision medicine. In spite of the expanding needs for adequate human-derived specimens in gynecologic cancer studies, there was no well-established biobank for gynecologic cancer. Biobanking requires effective and efficient management of not only tissue sampling and storage, but also systematic management of bioinformatics and distribution of high-quality research materials. We would like to introduce a biobank experience for biospecimens of common gynecologic cancer

Methods: Human specimen and data stored in the bank target primary gynecologic cancer cell line, tissue, serum, plasma, lymphocyte, urine, saliva and ascites. Specimen extraction was administered starting from 2012, and it was administered before or during the treatment using the low-invasive method with the patients agreement. Specimen quality and quantity was identified by classifying specimen by cancer type, acquired year and characteristic. Amount of specimen that was lent and distributed was verified, and published papers that were studied with these specimen were checked. Moreover, the institutions that signed work agreement with the Bank for collection of the specimen and academic interaction were verified

Results: Currently, specimen and data in the bank numbers total of 71,957. Starting from May 2012 to Nov 2020, 23,811 serum, 20,623 plasma, 6,084 lymphocyte, 99 whole blood, 3,866 frozen tissue, 7,173 ascites, 36 HOSE, 5,426 urine, 350 saliva, 440 cervicovaginal fluid, 32 TMAs and 2,932paraffin block units were stored.

Conclusion: Resources of gynecologic cancer bank is continuing to grow steadily since 2012, and quality resource is being developed through proper management. As such, these resources are utilized to publish a number of outstanding research papers. Likewise, request for distribution and lending for new researches is increasing. It is necessary to continue to acquire and manage resources continually to establish the mechanism and the treatment method of the gynecologic cancer that are not confirmed to this point. It is judged that it would be necessary to provide resources actively according to the fair and appropriate procedure of the related research institutions and academic community.

PG-13 Establishment of Eye Tumor Biobank to Provide Resources for Exploring New Biomarkers of Various Ocular Tumors

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Background: In addition to the lens, tumors can occur in almost all tissues of the eye. Lacking of effective biomarkers makes diagnosis of ocular tumors difficult. Biobanks are important resources for biomarker discovery and assay development. To support the validation of novel biomarkers and assays, we established a biobank to collect body fluids and tissue and associate data from subjects with ocular tumor diseases.

Methods: A standard operating procedure of collection, transportation, processing and preservation of human samples according to the experience of biobanks domestic and foreign have been established. Associated data had been collected and statistical analysis of the existing data had been performed.

Results: Cooperation between the eye tumor biobank and the Department of Ophthalmology, Xiangya Hospital, Central South University has been established, and various samples can be obtained. Currently, 708 samples are available from 78 subjects with 11 types of benign tumors and 12 types of malignant tumors, including hemangioma, schwannoma, retino-
blistoma, lymphoma, basal cell carcinoma, melanoma, sarcomas, etc. Of all the samples, blood, plasma and tissue samples account for 41.8%, 37.9%, 20.3%, respectively. Samples are stored at minus 80 degrees Celsius in the biobank. Nearly 2000 demographic information and clinical data are recorded.

**Conclusions:** A eye tumor biobank based on the cooperation with Department of Ophthalmology of hospital have been established, expecting to provide sample resources for exploring new biomarkers of various types of ocular tumors in the future.

**PG-14 The Science (and Art) of Biobanking: A New Graduate Level Course for Pathologists’ Assistants at the University of Toronto**

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**Statement of Problem:** Pathologists’ Assistants (PAs) are highly trained professionals who provide anatomic pathology services allowing Pathologists to render diagnoses. Their surgical specimen handling skills and expertise in identifying lesional tissue make PAs invaluable for tissue-based clinical research.

Many practicing PAs learned on the job. More recently, PAs are being trained in Applied Master of Science Programs in preparation for American Board certification. The Department of Laboratory Medicine and Pathobiology (LMP) at the University of Toronto has collaborated with the Department of Obstetrics and Gynecology to offer a new two-year professional Master’s graduate program to educate clinical laboratory medicine scientists in two fields: Clinical Embryology and Pathologists’ Assistant. The PA curriculum includes a novel course on biobanking consistent with the strong focus on academic skills in addition to clinical training. The first cohort of five PA students started in September, 2020.

**Proposed Solution:** The Science (and Art) of Biobanking’ is a 0.5 FCE seminar course offered 2 hours per week over 12 weeks in the second semester. The sessions include lectures by the course Director and guest speakers covering all aspects of biobank operations from inception to participant recruitment to specimen processing and data annotations to distribution of samples and data to research. Currently, the course is offered virtually with a Teaching Assistant who provides support to the students and Director. The primary reference for the course is ISBER Best Practices Fourth Edition and Addendum 1: Liquid Nitrogen-Based Cryogenic Storage of Specimens. Other resources include Canadian Tissue Repository Network National Standards and Canada’s Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018).

Students are evaluated through participation, quizzes, case study presentations and a final project group in which they present a biobank proposal. Feedback from the students is provided formally in class and through anonymous weekly surveys.

**Conclusion:** A new graduate level course on biobanking has been developed for PA students as part of a Master in Health Science Program. Because of their unique expertise in surgical tissue, it is anticipated that ‘The Science (and Art) of Biobanking’ will help provide PAs with the academic skills needed to make increasingly valuable contributions to clinical research.

**Informatics & Technology**

**PH-01 RepositoryOps – Accelerating Operational Tasks in the NIST Biorepository**


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Most sample repositories maintain a database including sample properties and locations. Commercial databases for this application are good at meeting the diverse needs of the community, but operational aspects of every repository can differ meaningfully and expose gaps in capabilities. This often means repositories spend their most valuable asset, staff time, covering the “data crunch” gap. Custom applications to leverage data stores can serve as work force multipliers by accelerating time-intensive data activities. Two of the many such tools developed and in use at the NIST Biorepository in Charleston, SC, USA, will be presented; together these return approximately 1,000 staff-hours annually to the NIST Biorepository. Both are built in the “shiny” package for the R language. (1) The “Freezer Visual Information System” (VIS) allows us to rapidly assess space utilization and allocation. Previously, oversight level information regarding storage distribution and freezer allocation was laborious to obtain and often fell back on institutional knowledge (e.g. “Freezer X is about half full”), while repository level estimations were considered impossible. Freezer VIS is a data visualization portal providing at-a-glance representations and precise space utilization metrics at all levels from the repository to individual boxes. Integrating this application into daily operations has made possible nearly instantaneous assessment of space utilization and allocation during sample accession, freezer management and lifecycle planning, and emergency responses (e.g. freezer malfunctions). (2) “Freezer Check” improves quality assurance and control practices by serving as a task curator for position record audits, allowing a running record of audit activities and a statistically sound estimate of position record accuracy. Previous practices were providing less than 1% aggregate assessment annually and leaving position discrepancies to ad hoc resolution. Integrating this application into our QA/QC practices also provided a scaffold to identify aspects of data management which could benefit from further data quality controls to improve QA/QC practices throughout daily operations. These tools, however, are not the main benefit; better understanding of the business and operational needs of a sample repository allows for building relatively simple software applications around solving those needs, saving repositories the one resource they cannot easily increase – staff time.

**PH-02 The Follow-up APP Construction of Nanjing Gulou Hospital Biobank**

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**Background:** In the era of big data, the deep integration of information technology and Healthcare industry promotes the development of mobile health. With the improvement of residents’ living standards and their demands for medical services,
the future medical services will also be transformed from the routine disease diagnosis and treatment mode to the patient-centered sustainable health management mode.

**Methods:** In Nanjing Gulou Hospital, the “Gulou Hospital APP” can complete intelligent consultation, registration, payment, query results and other steps through the mobile phone application software and mobile network, saving the time of patients and medical workers, and improving the efficiency of medical work. “Nanjing Gulou Hospital health care”, A WeChat public account for inpatients, also plays an important role in health education and doctor-patient communication. In the bases of the APP and WeChat public account mentioned above, the follow-up system of biobank was constructed. In the computer side, on the basis of “doctor management background” docking with the information management system of biobank, to obtain real-time donors into group information. On the mobile terminal, a follow-up module was added into the APP and WeChat public account.

**Results:** 1. For the patients, the mobile terminal of the follow-up management system, as a close “health steward”, can conveniently handle the service of medical appointment, can also be used to review the health status and diagnosis and treatment experience, and play a reminder function for the follow-up treatment and follow-up.

2. For doctors, intelligent allocation mechanism can help them to carry out long-term and continuous health management for specific patient groups, making communication with patients more efficient. For doctors with scientific research needs, and follow-up data of patients can be directly exported, and data mining/scientific research experiments can be carried out in combination with the solid samples resources of the biobank, so as to conduct relevant clinical and basic research on specific diseases.

**Conclusion:** The construction of follow-up APP reduces the cost of follow-up, ensure good compliance and high rate of follow-up, so as to achieve the perfect follow-up data, improve the follow-up data and clinical data availability and use value, which can better serve the hospital management and the transformation of scientific research.

**PH-03 Implementing Electronic Consent for Patients Donating Specimens to the Cancer Moonshot Biobank**

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**Statement of Problem:** The Beau Biden Cancer Moonshot initiative funds research in cancer prevention, diagnosis and treatment to accelerate progress in in key strategic areas of cancer research. The Cancer Moonshot Biobank has been established to provide a research resource for these key areas. The Biobank will engage patients receiving standard of care therapy at community hospitals that are part of the NCI National Community Oncology Research Program (NCORP), with emphasis on longitudinal sample and clinical data collection from over 1000 patients who represent the racial, cultural and socioeconomic diversity of the U.S. To overcome the limitations of traditional paper-based informed consent and to improve patient experience in the biospecimen donation process, an electronic consent (eConsent) system was adapted and integrated with the Biobank’s information management infrastructure.

**Proposed Solution:** The eConsent platform chosen for the program is Rave eConsent. This eConsent system is a patient-provider interactive platform that operates on smart phone/tablet and will later be available on a web browser. The platform allows medical providers to create patient accounts and manage the consent process for multiple patients. eConsent is available in English and Spanish. During the process of consent, the patient watches a brief video that provides an introduction to the Biobank program and the biospecimen donation process. The patient next reads through the informed consent form and flags sections where they would like further explanation from the medical provider administering consent. The provider reviews the flagged sections with the patient, before countersigning. Paper-based informed consent in multiple languages is available in the place of eConsent. On the back end, enrollment information is then passed onto the patient registration system to initiate patient registration. The consent record is also transferred to the Moonshot Biobank Participant and Provider Website, where the patient can access an electronic record of their signed consent form.

**Conclusion:** The Cancer Moonshot Biobank has designed a national infrastructure for biobanking that utilizes state-of-the-art technologies. The Biobank is the first NCI-sponsored study that implements eConsent and provides a model of operations for future studies employing eConsent.
maintained by biobank users with little IT knowledge. With a modest amount of time cost, our research staff were able to configure a secure and comprehensive participant-centric biobank-registry database that includes:

(a) permission-to-contact and dynamic itemised e-consenting,
(b) biospecimen-related data (a laboratory information management system, LIMS),
(c) patient-reported outcome/experience surveys (incl. migrating existing registry participants),
(d) linked medical record, government health data, and other participant data as required (e.g. wearable devices),
(e) significant form auto-population from consent data and previous forms for streamlined clinician/ biobank entry, and
(f) automated appointment and reporting tools for biospecimen/ data collection notification and tracking.

C: We recommend this web application for all biobanks, especially low budget, as a more cost-effective, fit-for-purpose and easily maintained solution to manage all biobanking and/or registry data.

PH-05 A Programmatic Solution Performing Deep Literature Searches to Demonstrate Biobank Value

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Background: It is of the utmost importance that biobanks demonstrate value to stake-holders. One method to achieve this objective is to have recipients of biomaterials (investigators) acknowledge the biobank when publishing their research. In this way, a simple literature search may show the contributions made by the biobank, and by building a bibliography, indicate the value of the biobank. However, investigators may omit, mis-attribute, misspell, or publish years after receipt of material rendering simple searches void. Employing a qualified librarian can overcome these deficits but come with high budgetary and institutional knowledge concerns. As an alternative measure, an informatics approach can be utilized. The Cooperative Human Tissue Network Eastern Division (CHTNED), a National Cancer Institute supported program, has developed an informatics approach to gathering this data through autonomous datamining of publically available resources.

Methods: CHTNED developed a program in PHP language and added it to Linux SystemD to run autonomously at set periods. This program iterates lists of investigators and queries a National Center for Biotechnology Information (NCBI) public webservice for objects written under that investigator’s name. If a reference is found, the program retrieves and stores the NCBI’s PubMed Central Identification. It then queries internal databases for any PMCID not presently on the biobank’s bibliography. For those not found, it retrieves the full-text object. The program parses the object looking for references using regular expression matching algorithms to catch the biobank’s name and any misspellings. If the biobank’s name is found, the reference is added to the bibliography. Any object without a reference is flagged for review by biobank staff for possible inclusion.

Results: Looking for the term /\[Cc\]./.\[Hb\]./.\[Tt\].\[Nn\]./.s/ or five other regex derivatives, using a sub-set of investigators (2,227), published within a 5yr period, the program found 60,924 PMCID. The program captured the PMCID, the document type (33), the journal of publication (4,609), keywords (212,000) and the full-text documents. From this, 72 articles were found indicating CHTN. A review is then performed by a biobank staff for verification

Conclusion: This proto-type program demonstrates that a deep literature search can be conducted to build a strong bibliography. This program saves resources and time and can exhibit value to a biobank.

PH-06 Update of Biobank Network for Promotion of Utilization of Biobank toward Realization of Genomic Medicine in Japan

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Background: In Japan, there are over 50 biobanks, which are hospital biobanks and population cohorts. Among these biobanks, we organized the biobank network connecting the three major biobanks (Biobank Japan, Tohoku Medical Megabank project, and National Center Biobank Network) and the major hospital’s biobanks for promotion of utilization of biospecimen and data. We developed and have provided a biobank cross-search service since October 2019. It enables researchers to search biospecimen and data by disease name, disease history, sex, and onset age. Quality control information and consent information are important for research use but were missing.

Methods: We examined the international standards for quality control information and consent information, and developed the minimum common data elements including them.

Results: We established the minimum common data elements including quality control information and consent information: sex, previous disease name/code, disease name/code, biospecimen type, age sampled, data type, vendor, platform for analytical data, quality control information and consent information. As for quality control information, we decided to use SPREC, BRISQ, and CAP as the international standards. As for consent information, we decided to use the GA4GH Data Use Ontology. We then developed an updated version of biobank cross-search system. We organized the biobank network storing over 420,000 donors, over 850,000 biospecimens, and over 200,000 analytical data with over 3,500 diseases.

Conclusion: We established the minimum common data elements including quality control information and consent information, and launched the biobank network storing over 420,000 donors, over 850,000 biospecimens, and over 200,000 analytical data with over 3,500 diseases. Utilization across various biobanks will be promoted by our biobank cross-search system and support of matching between academic/commercial users, and researches and developments toward realization of genomic medicine will be expected to be accelerated.

Innovative Technology

PI-01 The Value and Need of Comprehensive Consent. Benefits to Both the Patient and Biobank

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Consent Management is often viewed as a hurdle or an irritating task for doctors, researchers, and biobanks. The conversation that should take place is the value and benefit of consent to both the patient and the biobank.

This begins with the right software tools to support a wide range of consent types and components. Consent should not only be directly tied to every patient but every sample.

A biobank with comprehensive consent management in place becomes a well-rounded resource (not merely a service) to both their institution and external researchers. This benefits their ability to obtain grants as well as establish additional cost recovery activities. It also helps support recruitment strategies for biobanks, whether general or disease specific.

Secondly, patients benefit as they gain a better understanding of how their samples will be used, the benefits to society, and most importantly to themselves. Biobanks seeking consent for samples owe it to patients not to utilize anonymized data taking away the value of the research to the individual. No patient should be left behind and should be offered transparency.

The use of pseudonymized (rather than anonymized) data, which maintains the connection to the patient, also provides biobanks the transparency to understand the value of the samples they hold. These connections also help researchers identify additional opportunities for research, or even trends in the community.

Biobanks are more than sample management and should not be viewed as service providers and freezer farms managed with excel sheets. They provide the foundation for an institution’s research. This is where we need a focus on more comprehensive consent management.

Biobanks are the archive of future medicine, unlocking that value starts with consent.

PI-02 Innovation in Sensing Technology and Application Resources

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The evolution of sensing technology has experienced significant change with low-cost integrated electronics. Inexpensive microcontrollers with integrated data conversion technology have resulted in the smart sensor becoming increasingly more affordable. With this technology, coupled with the pervasiveness of the internet, a new era of sensing technology is ushered into use. It is referred to as IoT (Internet of Things). These devices are now being configured to communicate to cloud-based servers, eliminating the need for hardware to be installed locally. With cloud storage and the available computing power in the cloud servers both artificial and business analytics may be applied to the collected data.

The monitoring solution’s objective is the first and foremost accurate representation of the stored good. The monitoring process, recordation and display of the collected data, trending, and alert notification based on the trending are a must. Equally as important as the accurate representation of the stored good temperature is reliable alerting. False-positive alerts cause alert fatigue; missed alert conditions can result in stored good being compromised.

This paper explores the tools available for data collection, the methods for accurate representations of the collected data, and an introduction into the analytics that can be derived from the data stream.

PI-03 Infinity Biologix – How did a Biorepository Pivot from Biobanking to COVID Testing and Vaccine Storage and Distribution?

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RUCDR Infinity Biologics (now IBX) has provided the global scientific community with the highest quality biomaterials, technical consultation, complex assays, and logistical support since 1998. On August 17, 2020, Rutgers University completed the sale of RUCDR to create Infinity BiologIX. As Infinity BiologIX, we have the same core mission, advancing research; collecting, storing, and providing high quality biomaterials; providing complex assays and services; and large scale diagnostic testing.

As a research organization and a traditional biorepository, with several decades of experience in offering diagnostic assays, IBX was approached by local & state entities to support the global community in expanding COVID testing by offering rapid testing to enable clinicians and patients to make critical decisions. In early 2020, during the height of the pandemic, IBX developed the COVID RT-PCR diagnostic assay. It received FDA Emergency Use Authorization in March 2020 as the first approved saliva diagnostic test and the first test approved for home use. IBX leveraged decades of experience in molecular genetics to overcome issues in working with saliva, such as its viscosity and abundance of RNA-degrading enzymes.

To scale the capacity, IBX received support from Operation Warp Speed and a loan through RUCDR. IBX was able to purchase multimillion-dollar laboratory automation to automate the extraction and amplification of each sample using qPCR techniques, requiring IBX to double the lab’s workforce almost overnight. IBX also collaborated with two companies, Spectrum Solutions and Accurate Diagnostics Labs, to oversee the manufacturing and distribution of kits, while IBX handled testing and analysis. Since March 2020, IBX has tested 5 million samples through a number of direct to consumer partners including Vault Heath and currently has the capacity to test over one million samples a month, playing a critical role in saving many lives, and providing a practical tool for pandemic control.

As the FDA approved several vaccines including Pfizer and Moderna, IBX went a step forward in the fight against the global pandemic by offering state-of-the-art vaccine storage, distribution, and robust cold chain solutions. IBX collaborated with Stirling Ultracold to provide temperature flexibility using modular, ultra-cold freezers fitted with monitoring systems and utilized mobile ULT25 freezers, dry ice, cold packs and data loggers to maintain stability during transportation.

Repository Management

PJ-01 The ISBER/ASCP BOC Qualification in Biorepository Science (QBRS) Examination is Available for Application Online

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Background: Well-trained repository staff are essential for assuring high-quality research specimens. ISBER, the leading international biobanking society, and ASCP BOC (American Society for Clinical Pathology Board of Certification), an organization providing excellence in global medical laboratory professional certification, have developed a shared online qualification examination through which individuals may earn a biorepository qualification credential, the Qualification in Biorepository Science (QBRS).

Methods: QBRS Workgroup (WG) was established as a standing committee of the ASCP BOC. The WG’s task was to develop, review and update the biorepository qualification examination itself, perform job task analyses, develop the examination content guidelines, eligibility requirements, and candidate professional experience documentation forms needed for the QBRS credential. All QBRS credentials awarded will be time-limited and be revalidated every three years with documentation of continuing education or other educational activities as defined by ASCP BOC. ISBER and ASCP BOC responsibilities have been established, and annual review will be performed.

Results: A Memorandum of Understanding was developed and signed. The QBRS document development was completed and the QBRS credential program application process was available online for applicants in January 2020. At September 30, 2020, 12 applicants have taken and passed the exam with another 4 in process.

Conclusion: ISBER has joined forces with ASCP BOC to develop a QBRS credential program. ASCP BOC is an experienced, well-recognized organization for certifying professional competency among individuals worldwide, while ISBER Workgroup participants provide content knowledge and biobanking expertise. This agreement has allowed the development of a global QBRS credential program, requirements of which are essential for the future of sustainable quality biobanking. Further details including requirements for qualification and an FAQ document are available on the ISBER and ASCP BOC websites and will be elaborated on presentation.

PJ-02 Biobanking during COVID-19: An Academic Institutional Biorepository’s Experience

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Statement of the Problem: The Houston Methodist Research Institute Biorepository is a centralized biorepository at the Houston Methodist Hospital System. The COVID-19 pandemic hit the biorepository with full force and forced it to rethink its operational priorities. The Biorepository had to pivot fast to cope with the inflow of the COVID-19 specimens while managing the additional ethical, safety and specimen handling guidelines associated with the everchanging COVID-19 landscape. The Biorepository’s workload increased multi-fold with institutional mandate on collecting, processing and storing residual blood samples from all COVID-19 patients coming to the seven Houston Methodist hospital entities. Sample processing, storage and release for the urgent convalescent plasma therapy research study, as well as for the COVID-19 employee surveillance were also managed by the biorepository. The Biorepository was also releasing large number of processed samples on a regular, priority basis to the clinical lab for validation studies on diagnostic platforms and kits. A multitude of new COVID-19 related research studies and the upgrade of the Biorepository Information Management System, that had just got off the ground as COVID-19 stuck, were also handled.

Proposed Solution: The biorepository deployed 5 temporary staff from the institutional labor pool to cope with the initial wave of COVID-19. The clinical lab staff came in to help when the temporary staff wasn’t available. Staff worked after office hours and on weekends to complete the work. The Director and Manager worked on the bench at times to give a helping hand to the staff. Quick changes to the workflow were implemented. Lists to capture the influx of COVID-19 patients were generated with the help of the Pathology Informatics Group. The upgrade of the Biorepository Information Management System continued intermittently as and when COVID-19 provided a temporary breather.

Conclusion: The Biorepository was able to tackle the COVID-19 challenge all thanks to the extraordinary work performed by its permanent and temporary staff. The ongoing support provided by Pathology Informatics Group and Houston Methodist Research Institute IT Group helped the Biorepository immensely in navigating the sample accessioning and related IT challenges. Institutional Executives were very prompt in addressing the Biorepository’s needs. The Biorepository’s COVID-19 collections are still ongoing as subsequent surges emerge.

PJ-03 Challenges and Risks Facing Qatar Biobank Staff during COVID-19 Biorepository Project

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Background: Qatar Biobank (QBB) launched the COVID-19 biorepository project to enable medical research on the COVID-19 outbreak in Qatar throughout collection of biological samples and information from large numbers of patients infected with COVID-19 in Qatar. This will facilitate future studies that could illuminate the pathophysiology mechanisms and identify markers of disease prognosis as well as describe the clinical features and epidemiology of COVID-19 in Qatar.

Method: A survey has been conducted and distributed to Qatar Biobank staff to address and highlight the risks and challenges that QBB staff experienced during the COVID-19 biorepository project. The survey consists of ten questions analyzed using trend analysis.

Result: The survey result shows the challenges that Qatar Biobank staff experienced during the COVID-19 biorepository projects are missing their daily social interaction with their colleagues and feeling anxious working in a new environment in a way different to their usual pattern. In addition, feeling anxious and fear from being infected as well as being able to comply with infection control protocol and maintain required precautions. Moreover, resistance to change and inability to adopt the new work type. Furthermore, shortage in supply and being able to provide high quality and safe resources in a short period of time and in the high demand of the world. Additional to that getting limited or difficult to access technology resources especially in the recruitment sites. Additionally, feeling uncertainty and anxiety from being unable to achieve managers expectation to accomplish projects’ desired outcome.
Conclusion: The conducted survey captured number of challenges that Qatar Biobank staff experienced during the COVID-19 biorepository project from different aspects. Addressing theses challenges is highly important and recommended to find solutions and overcome these challenges to ensure staff satisfaction and therefore high quality of work.

PJ-04 Planning and Interventions to Maximize Cold Storage Appliance Life and Performance
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Laboratory refrigerators and freezers maintain low temperatures, protecting sample and reagent integrity and functionality. Power outages and mechanical failures resulting in elevated temperatures in the refrigerators and freezers puts the samples at risk. Proper environmental conditions and setup, storage and organization, and consistent ongoing maintenance promotes maintaining the correct temperature and maximizes the life span of the appliance. Initial setup of the freezer optimally includes providing emergency power of the correct voltage for the appliance. Additionally, the room should have generally level floors and the appliance should be leveled to ensure the door closes when at rest and the door gasket creates a tight seal to prevent frost buildup. In addition, the room should have appropriate air conditioning capabilities to maintain the correct temperature and remove excessive heat generated by the appliances. Storing the correct number of samples and boxes in the appliance and evenly distributing them throughout the freezer promotes air flow and maximizes a consistent temperature throughout the appliance. Defrosting the freezer on a regular basis prevents excessive frost buildup, promotes efficient sample retrieval and increases air flow. Implementing a reliable and intuitive system to track the locations of samples in the appliance increases organization and minimizes the time required for the door to be open when finding and removing the target samples. Tracking the intervals when the door is open enables the users to limit subsequent door openings and provides adequate time for the appliance to return to the target temperature. Preventive maintenance including cleaning the compressor coils and the filter promotes air flow maximizing mechanical performance. Performing bi-monthly inspections of the appliance will identify potential problems and to allow proactive repairs. Real-time temperature monitoring and alerts will identify temperature excursions and notifies staff when the appliance needs attention and if samples need to be moved to a different storage location. Correct setup, use, and maintenance of a cold storage appliance maximizes performance and protects the integrity and functionality of samples and reagents.

PJ-06 Methods for Analyzing and Documenting Costs and Benefits of Scientific Collections
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Background: The Interagency Working Group on Scientific Collections (IWGSC) is part of the White House’s National S&T Council, and in 2010 it was charged by OSTP and Congress with identifying methodologies for estimating and documenting costs and benefits associated with Federal scientific collections. These collections span many disciplines and they include plant, animal and microbial biobanks.

Methods: IWGSC convened a Study Group of federal researchers, collection managers, economists, and budget/policy specialists. They invited specialists with experience in cost/benefit analyses to present case studies related to collections, conducted via webinars over a six-month period. The resulting report was reviewed and improved by IWGSC’s agency representatives.
Results: The Study Group’s report (see iwgsc.nal.usda.gov) describes the types of collections that are owned, managed, and/or funded by Federal agencies. Federal biobanks are considered “institutional collections” that are accessible to researchers for diverse uses. The report presents six services that collections can provide: accessioning; preserving and maintaining; documenting additions; providing access to users; data curation; and education and outreach. Collections vary in the number of these services they provide, and the intensity of effort in each. Operating costs can be estimated using the framework provided by these services, using methods presented in the report. The report then presents five methods for estimating and documenting the benefits generate by these services. One or more case studies are presented with each method. Each method has strengths and weaknesses and agencies can select methods that best address their missions, management systems, and the audience(s) for their performance metrics. The report highlights the connections between the services provided by a collection and the types of benefits it can generate.

Conclusions: Methods for estimating and documenting costs and benefits have two general functions. First, they support evidence-based collection management when setting performance goals and allocating support among the services offered. Second, they can improve the ability of collection staff to explain the value of their collections and the support they need to generate returns on those investments. While the focus of IWGSC is federal collections, the report’s findings generally apply to all kinds of collections/biobanks.

PJ-07 Newly Developed Qualification System to Assess Personnel Competency in Biobank Activities in Japan

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In September 2020, the Council for Industrial use of Biological and Environmental Repositories (CIBER) announced the launch of a new qualification system to assess personnel competencies in biobank activities. The examination for qualification as a “Biobank Technical Administrator (BiTA),” is conducted in Japanese, and mainly targets personnel working at biorepositories located in Japan. The initial examination will take place online on March 28, 2021.

In accordance with the rising number of biorepositories, the number of biobanking personnel has increased. Operations at biobanks and bioresource centers involve in a wide range of specialized fields, including the processing of a wide variety of samples, quality control, data generation and management, sample/data storage, quality management, and research consultation. The BiTA qualification will aid the development of skilled human resources, by providing an objective index of personnel skills and competencies.

The recent publication of ISO 20387 indicates that biobanks have become an indispensable global life science research infrastructure. The stakeholders within the biobanking community, including CIBER members, translated ISO 20387 into the local language, and the Japan Accreditation Board (JAB), the head organization of third-party conformity assessment, is currently developing a biobanking accreditation scheme. CIBER aims to contribute to the BiTA qualification and the development of the domestic accreditation scheme in close collaboration with JAB.

Globally, the International Society for Biological and Environmental Repositories (ISBER) has been issuing Best Practices: Recommendation for Repositories, since its establishment. ISBER recently co-developed the Qualification in Biorepository Science (QBRS) personnel certification, partnering with the ASCP Board of Certification. The developers of the BiTA qualification referred to the QBRS as a model in designing the test structure and overall concept. To further enhance the BiTA qualification, it would be ideal if a formal alliance with QBRS is realized in the future.

CIBER plans to strengthen the structure and concept of the BiTA examination to be used as proof of the qualifications of both personnel and facilities, to foster the development of professional personnel and advance the progress of biorepository-based scientific research.

PJ-08 Optimizing Tissue Acquisition for Biobanking through Patient Prescreening: Lessons Learned at a Tertiary Cancer Center Biorepository

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Background: Efficient patient screening, informed consent and successful biospecimen acquisition are fundamental to the biorepository. Correlation was performed to better understand the screening-consent-tissue acquisition workflow. We evaluated optimization opportunities for effective patient enrollment, efficient time management and better tissue acquisition.

Methods: Consent and tissue acquisition data from Northwell Health Biospecimen Repository (NHBR) was evaluated for June-December 2020. NHBR workflow has two integral teams: a) Research coordinators, performing initial screening, enrollment and consenting, and b) Anatomical Pathology, for specimen examination, acquisition and storage, and distribution. Teams also coordinate communication with operating room, NHBR data management, specimen distribution, and quality monitoring and reporting. Successful biospecimen acquisition was correlated with patient screening, enrollment, and informed consent outcome.

Results: 615 patients were prescreened based on information from the clinical tumor boards, ICD -10 screening, direct physician referrals and less commonly as direct request from the patients. 78.54% (n = 483) patients met NHBR inclusion criteria and were consented. 15.61% (n = 96) of prescreened patients declined consent and 5.85% (n = 36) patients were excluded due to loss of follow-up or not meeting inclusion criteria based on presurgical imaging and pathology diagnosis. In-person or telephonic consent was acquired within 48 hours prior to procedure in 87.65% patients. E-consent was used in minority of patients. Following the patient consent, fresh biospecimen was acquired in 87.65% patients. E-consent was used in minority of patients. Following the patient consent, fresh biospecimen was obtained from 87% of patients. Tissue collection was aborted in 13% (n = 63) consented patients, most commonly due to the small tumor size entirely needed for diagnosis, treatment modification or benign diagnosis following frozen section examination and lesion being an infection/abscess. Other reasons
included consent withdrawal, inadvertent tissue exposure to formalin, or rescheduled procedure.

Conclusions: Our data reinforces the premise that the biorepository success rate relates to having a proactive approach to the patient screening. Clearly defined team roles, establishing measurable quality metrics, continuous quality monitoring, and coordination between teams are essential for overall process improvement. Opportunities may exist in clinical lead generation, community education and awareness, E-consenting and operating room coordination.

**PJ-09 IT Solutions and Integration in DonorQuest Application for Investigators Requesting Historical, Real-time, and Projected Sample Collection Data in the Biorepository Setting**

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Background: Biorepositories are often asked to supply real-time or historical collection data and make predictions on future collection capabilities for investigators trying to secure funding for their research. Frequently, the request for information (RFI) from the biorepository is made by the investigator a few days or hours before the submission deadline, resulting in potentially unrealistic predictions of donor availability.

Objective: The immediacy of digital information is challenging and is becoming a requirement for most organizations in order to meet the demands of the investigators. In short, advances in technology have trained us to expect instant access to data at any time we require it. Data collection and management within the biorepository should be viewed in the same manner as any other service-related industry. The goal is to be more productive in less time and provide accurate data as it is requested and returned to the end-user with minimal effort.

Method: The Cooperative Human Tissue Network at Vanderbilt University Medical Center (CHTN-VUMC) has operated as the Western Division of CHTN since 2001, providing investigators with remnant human biospecimens for basic research and discovery. Utilizing historical data, we have developed two real-time data analytic systems to aid investigators in obtaining information and streamlining the reporting process.

On-Demand Prediction Analytics (ODPA) provides prediction on future collection capabilities based on historical data.

DonorQuest Continuous real-time Analytics (CoA) provides users with a real time data on current fulfillment capabilities of DonorQuest.

Results: The systems allow the investigator to search specific criteria and obtain both future predictions and real-time current capability on specimen procurement by anatomic site and disease type; preparation; QAQC validation or samples in the QAQC process.

Conclusion: Delivering and exposing real-time biospecimen procurement data may have an immediate benefit by allowing investigators to determine if a resource can supply the required samples for their research.

**PJ-10 Emergent Transformation of Cancer Center Tissue Biobank to a COVID-19 Biospecimen Processing Facility: Creation of Shared Institutional Resource**

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Introduction: Establishment of a COVID19 Biospecimen Processing Facility (BPF) was undertaken, leveraging an existing Northwell Health Biospecimen Repository (NHBR). The purpose was to support COVID19 clinical trials and create a resource of biospecimens with clinical metadata. This institutional resource is envisioned to have impact on scientific inquiry, including innovation in clinical care and investigation of disease mechanisms. We present our experience, challenges, and scientific opportunities.

Materials/Methods: NHBR pivoted from a cancer focus to COVID19, by establishing a dedicated BPF, redeveloping existing personnel, recruiting additional volunteer health care workers, and building the IT infrastructure to support clinical trials and establish a COVID19 repository.

Results: COVID19 biospecimens were obtained from three tertiary care facilities within Northwell Health; with inpatient COVID19 admission peak of 550, 711 & 304. NHBR staff of 6 Research Coordinators and 4 Pathologists’ Assistants was supplemented by 22 volunteers. The Regeneron-Sanofi clinical trial to evaluate the efficacy of IL-6 inhibition with Sarilumab laid the framework for biospecimen processing. Additional COVID19 clinical trials continue to be supported by the BPF/NHBR. For biospecimen accrual, system data warehouse records were mined to identify biospecimens from COVID19 inpatients. A committee consisting of clinicians and clinical researchers provided guidance in developing the COVID19 BPF. The NHBRs preexisting global IRB-approved collection protocol obviated the need for an additional COVID19 biospecimen IRB protocol, which allowed for rapid activation of sample procurement. Accrual of 40,400 aliquots (serum, plasma, and whole blood) from 3,815 unique patients, including 366 COVID19 dececents. Viral Transport Medium (VTM) remnant specimens from more than 40,000 positive patients were retained.

Conclusions: A database of remnant/discarded VTMs was established secondary to the patient care. Having a robust institutional research infrastructure is critical for preparedness and rapid response to the large-scale public health threat. Our call to action, rapid deployment and repurposing of existing assets enabled our health system to establish valuable resource that may enable us to further advance COVID19 related research. Limitations in our effort were: suspension of COVID19 biospecimen operations due to a shortage of human capital and a 4-month delay in procuring funding.

**PJ-11 IT Solution in DonorQuest Application to Provide Real-time Alerts and Monitoring of Prospectively Procured Biospecimens**

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Background: Prospective biospecimen collection in biorepositories happens primarily behind the scenes. Investigators are not typically aware of the entire process of sample collection and the subsequent movement of these specimens through the biorepository before they are released. Certain processes can delay release of specimens including patient diagnosis, ancillary testing, and QAQC analysis.
Objective: To enhance user experience, IT staff developed a tracking mechanism to provide the investigator real-time status updates of prospectively procured samples at every step in the process.

Method: The Cooperative Human Tissue Network at Vanderbilt University Medical Center (CHTN-VUMC) has operated as the Western Division of CHTN since 2001, providing investigators with remnant human biospecimens for research and discovery. DonorQuest is a web-based application designed by CHTN-VUMC to manage all aspects of tissue procurement workflow. This application allows users to request specimens from appropriate donors with upcoming scheduled surgical procedures. Once the investigator has expressed interest in a particular donor and sample type, they are provided real-time updates on the movement of the specimen from start to finish. This begins when the patient is consented, then sample procurement, QAQC analysis, and finally the tracking number of shipment. Status and progress of requested procurement can be viewed in investigator portal of DonorQuest. Additionally, if investigators subscribe for text alerts, SMS is sent every time there is an update in the procurement step.

Conclusion: By providing the investigator a glimpse into this process, it automatically creates a positive experience for the investigator and eliminates confusion about when samples will be available for their research.

Repository Standards

PK-01 Update of ISBER BAT Based on ISBER Best Practices 4th and Addendum on LN2 Based Cryogenic Storage
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Background: The International Society for Biological and Environmental Repositories (ISBER) Biobank Assessment Tool (BAT) is a questionnaire aimed to help biobanks to evaluate how well they comply to the ISBER Best Practices. The BAT was deployed for end users in 2011, since then ISBER has published the 4th edition of the Best Practices and the Addendum on Liquid Nitrogen (LN2)-based cryogenic storage (Addendum 1). In addition, a new international standard-ISO 20387:2018 Biotechnology-Biobanking-General requirements for biobanking was published in 2018. In order to stay up to date the BAT needed an update.

Methods: The BAT was updated in accordance to the ISBER Best Practices, 4th edition and the Addendum 1. In addition, where applicable, the results will also include references to the ISO20387.

Conclusion: The updated BAT will help biobanks to assess their compliance to the ISBER Best Practices, the Addendum 1, and on a higher level also the ISO20387 biobanking standard. The BAT can be used repeatedly, which allows follow up every year, giving it a natural place in any QMS where implementation and follow-up of quantitative indicators are required.

Responsibilities

PK-02 Preparation of a "Translation kit" for ISBER Best Practice 4th edition for Biobankers in IPR Region
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Statement of the Problem: Various standards and/or guidelines for biobanks and or biorepositories are provided by diverse parties. Most of these are written in English. Although contents of these guidelines are good, it is extremely inconvenient to implement these English written guidance into routine practices for biobankers in general in non-English language regions.

Proposed Solution: Recently World Health Organization (WHO) revised International Classification of Diseases 11th Revision (ICD-11). When providing this ICD-11, WHO is providing a translation kit for potential users of ICD-11. This procedure inspired us to do similar contribution in our files. All the Regional Ambassadors (RAs) and Director-at-Large (DAL) in Indo-Pacific Rim (IPR) region were agreed to take this direction and prepared a similar translation kit for potential ISBER Best Practice (BP) 4th edition for biobankers in general in IPR region. We are preparing a translation kit with languages of Hindi, Indonesian, Vietnamese, and Japanese.

Conclusion: This translation kit is a sort of comparison table with various languages. If this attempt is appreciated with general biobankers, this attempt could be expanded to other languages.

PK-03 The Importance of Quality Control In Biobanking: Correlating Diagnostic Accuracy Between Gross and Histologic Classification of Tissue Samples Obtained and Released for Research
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Background: The Duke BioRepository and Precision Pathology Center (BRPC) has been a member of the Connective Human Tissue Network (CHTN) since 2019. Since then, the
procurement and release of tissue to various researchers within the CHTN has been vital to studies globally. Since the BRPC tissue procurement involves grossly identifying desired tissue for various processing methods, a rigorous histological quality control mechanism is needed to ensure the diagnostic accuracy of the specimens. In 2019, the BRPC instituted the use of quality control "mirror-images"; every collected specimen is bisected with half stored in the desired format and the other half stored as an FFPE block with a hematoxylin and eosin (H&E) stained slide. This process allows pathologists to verify the diagnosis of each procured tissue sample. This study evaluates the accuracy of grossly identified tissue and compares the final review diagnosis given by certified pathologists to determine the importance of quality control in the identification of research tissue.

Methods: All BRPC-facilitated specimen collections for the CHTN were evaluated, and available quality-control H&E slides reviewed by a certified pathologist. A comparison was made between the initial impression of the gross samples received and the final quality control diagnosis given by certified pathologists.

Results: The BRPC facilitated 257 unique specimen collections for the CHTN, resulting in 272 distinct samples collected and quality control "mirror images". To date, 16% (43/272) of CHTN quality control H&E slides have been reviewed by a certified pathologist. The gross tissue impression was accurate in 81.4% (35/43) and inaccurate in 18.6% (8/43) of specimens collected, and researchers were notified.

Conclusions: The accuracy of a suspected grossly-identified tissue released for specific research investigations as compared to the conclusive diagnostic results from microscopic examination is essential to the success of a biobank. The downstream data that researchers generate from the samples they are given is pertinent to the samples they actually receive. Review of quality control H&E slides is ongoing, but based on the percent-accuracy to date we can conclude that gross identification of samples is a reliable method to select tissue for research and that quality control provides value for researchers to ensure that they are able to obtain valuable data for their projects based on the receipt of requested tissue.

PK-04 Quality Management System to Generate Key Performance Indicators for Biobank Effectiveness

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Introduction/Background: Human DNA samples with associated clinical data are increasingly recognized as invaluable resources for biomedical research. Biobanks support the scientific community by collecting and storing high-quality biological samples for subsequent research, including genomic analyses.

Quality control (QC) tools help to evaluate sample characteristics, including their fitness for purpose, long term functionality, purity, and integrity for genomic applications. McCain GU BioBank (MGB), focused on genitourinary (GU) oncology samples in Canada, has employed the “Standard PREanalytical Code” (SPREC) to record pre-analytical factors that determine the integrity and fitness-for-purpose of biospecimens and their derivatives.

Methods: The QC analysis was performed by an external party, the Integrated Biobank of Luxembourg (IBBL)

Blinded buffy coat and urine cell pellet samples from the GU cohort with clinical endpoints were subjected to QC analysis. Samples with different age of storage (<1, 4-5, and 9-10 years) were used to assess the quality of samples when the pre-analytical parameters had not been individually documented. DNA was extracted from buffy coat and urine pellet samples. Total and double stranded DNA yield, purity and integrity from both type of samples have been analyzed and used as QC metrics to characterize the samples.

Results: The results were analyzed in relation to the duration of storage and other pre-analytical parameters. Overall, results correlated well with documented pre-analytical conditions of the samples. Duration of storage in liquid nitrogen up to 10 years did not adversely impact the quality of DNA extracted. Approximately 90% of the extracted DNA samples from buffy coat were found to have a DNA Integrity Number (DIN) in the range of 8-10. Total DNA yield was greater than 14 ng/100 µL of buffy coat in approximately 70% of the samples. Approximately 97% of extracted DNA samples had A260/A280 ratio >1.6.

Conclusion: Advances in molecular biology techniques, such as genomic analyses and sequencing, would not have been possible without high-quality DNA obtained from patient populations. Purity, integrity, and usability of DNA derived from biospecimens stored in MGB were assessed, and samples were found to be appropriate for genomic analyses. Through this collaboration with IBBL, MGB has confirmed the high-quality of the stored samples and their fitness for research into genomic biomarkers.

PK-05 Deposit and Distribution of Human Pluripotent Stem Cell Lines in the Frame of the Spanish National Stem Cell Bank from the ISO 20387 Perspective

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Background: There is a legal obligation to register and deposit in the Spanish National Stem Cell Bank all the human pluripotent stem cell lines (hPSCs) generated in Spain, guaranteeing their preservation and hence their availability and distribution for biomedical research. This National Bank has a network structure with 3 nodes, being the Andalusian Public Health System Biobank the Central Node. When a cell line is received in the Biobank, Mycoplasma test is performed, cell identity is checked by genetic fingerprinting and chromosomal status by karyotype, before expansion of the cells to generate a stock available for distribution. The Andalusian Public Health System Biobank has these operations included in its Quality Management System certified according to ISO 9001:2015.

Methods: In order to confirm if biobank operations related with deposit, testing, storage and distribution of hPSCs would be competent from the ISO 20387 perspective, analysis of the workflow and procedures covering life cycle applied to this biological material and associated data has been developed.

Results: Scope of biobanking operations has been established and procedures and documented information involved in the workflow have been identified and revised to ensure compliance with relevant requirements. When it has been necessary for compliance with ISO 20387, new actions, documents or
records have been designed for critical equipment, personnel, quality controls or risks involved in the processes of deposit, testing, storage and distribution of hPSCs.

Conclusions: The analysis performed give answer to the Option B of Clause 8 of ISO 20387 about quality management system requirements, to operate biobanks in accordance with both ISO 9001 and ISO 20387.

PK-06 The ISBER Best Practices: Recommendations for Repositories in Vietnamese

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In Vietnam, many public or private health organizations currently have a high demand to establish biobanks to develop personalized medicine and regenerative medicine. However, it may become difficult due to language problems. There was no Vietnamese version of any international standard procedures or good/best practices available. Besides, biobank curriculums are rare in educational institutes. This fact leads to the lack of a systematic guideline and method to set up a cryopreservative repository. Therefore, translating the ISBER 4th Best Practices into Vietnamese is needed. In this presentation, the process of Vietnamese translation will be shown and discussed. The translation objectives are to identify the vital role of biorepositories, their associated services, and applications and bring knowledge and experiences of repository professionals at various organizations from around the world to Vietnamese repository managers and staff. The translation board does believe that this document will become a helpful resource and reference to many organizations in Vietnam where have a high demand for establishing and operating a biobank.


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Background: Prior to the publication of ISO 20387:2018 General requirements for biobanking, biobanks seeking accreditation to international standards could do so through compliance with ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. As a specialized ISO standard is now available, many biobanks who are already accredited to ISO/IEC 17025 question the benefits of seeking accreditation to ISO 20387 for their biobanking services, either in concurrence with or instead of their accreditation to ISO/IEC 17025.

Methods: We performed a comparative analysis of the two standards using a crosswalking process to identify matching clauses and unique content.

Results: As ISO 20387 follows the same format as ISO/IEC 17025, both with a heavy emphasis on the utilization of a quality management system, strong similarities have been found for the sections covering general, structural, resource, and management system requirements. Each standard’s respective section on process requirements, however, has been structured differently. ISO/IEC 17025 identifies the individual principles of quality which pertain to testing and calibration processes, whereas ISO 20387 specifically identifies biobanking processes and lists the relevant quality requirements for each. This results in ISO 20387 having several clauses which describe the requirements for the same quality principle but put into the context of each biobank process. This difference embraces the complex and varied structures of biobanks, allowing flexibility for processes on scope while focusing on sample and data traceability. In contrast, ISO/IEC 17025 provides more streamlined requirements which are intended to be applied to each process on scope with an emphasis on appropriate testing methods and accurate testing results.

Conclusions: Biobanks seeking compliance to ISO 20387 may find that few changes to their ISO/IEC 17025 compliant quality management system are necessary, yet these are critical for ensuring the fitness for intended purpose of the biological material and associated data collected under their care. Consequently, the changes required for compliance to ISO 20387 can help increase user satisfaction and confidence in the biobank’s products and services.