Alberta Children's Hospital BioCORE Policy Document

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Contents

1. About the BioCORE

The Alberta Children's Hospital (ACH) BioCORE (referred to as the 'BioCORE') is a not for profit biobank and bioanalysis core facility located in the Alberta Children's Hospital and the University of Calgary. The BioCORE is operated under the expertise of the Director, Dr. Michael Esser, MD and Co-Director, Dr. David Sinasac, PhD. The BioCORE currently operates from 8:30AM – 4PM, Monday to Friday, with flexibility depending on client needs. The BioCORE currently serves over a dozen Principal Investigators and Clinicians working on various research studies with multiple sample types and storage conditions. Our primary storage temperatures currently include -80^{o}C and Room Temperature.

The BioCORE is an Alberta Children's Hospital Research Institute and University of Calgary, Department of Pediatrics, Neurocritical Care Program-funded poly-user bioanalytical core and biobank. The biobank is currently of small-medium size (capable of storing tens of thousands of biospecimens) and prospectively collecting and generating linked data relating to the donor, biospecimen, disease, treatment, and outcome.

This policy document outlines the basic BioCORE services, access policies, samples management policies, and data management policies. Should you have further questions about any of the policies listed in this document, please contact us (contact information is included on the last page of this document), and we would be happy to assist you.

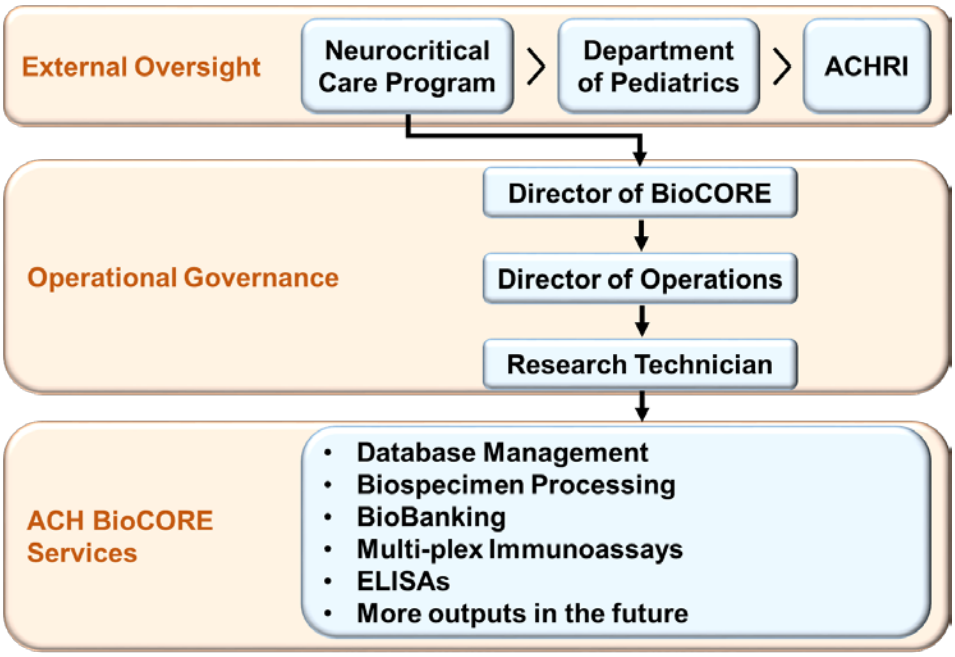
2. Our Vision

To establish a research-oriented, Canada-wide biobank and bioanalysis core facility for pediatric research. Our goal is to support and generate clinical research insights that ultimately improve pediatric health.

3. Roles & Responsibilities

Dr. Michael Esser – Director of BioCORE
Dr. David Sinasac – Director of Operations
Matthew Rosin – Research Technologist
To be determined – BioCORE Review Committee Member (scientific expert)
To be determined – BioCORE Review Committee Member (scientific expert)
To be determined – BioCORE Review Committee Member (lay person)

4. Governance Structure Overview



5. Research Priority Areas

The BioCORE was established in 2014 as part of a new Pediatric Neurocritical Care (NCC) Program initiative at the Alberta Children's Hospital (ACH). Within the University of Calgary's Department of Pediatrics, the NCC program is designed to help improve bedside care for children with neurological disorders and to provide support for pediatric translational research. The ACH BioCORE serves as a major infrastructure platform for the NCC program with a firm direction to become a biobanking and bioanalysis core facility for all pediatric health research at the University of Calgary and the Alberta Children's Hospital.

The research priorities of the BioCORE are linked with the goals of various other organizations. Because of this, the services (see section **6. Services** for more details) offered by the ACH BioCORE are subject to application and review with significant consideration for the following research priority areas:

Priority A: Pediatric Neurology
Priority B: Pediatric Health (other than neurology)
Priority C: Animal research relevant to pediatric health

Please note that BioCORE personnel will be considering these research priorities in addition to many other factors when reviewing an application for services. Note that the BioCORE does not apply a standardized weighting to these research priority areas. Please see section **6. Services** for more details on how applications will be assessed.

6. Services

6.1 Arm 1: BioBanking service

We offer biospecimen storage to support to Principle Investigator (PI-) driven human research studies in pediatric health. This service includes research study-specific biospecimen data entry into a secure sample management database, biospecimen storage using unique barcodes and freezer storage locations, highly regulated sample tracking (ie. sample 'check in' and 'check out' of freezers), and optionally may also include biospecimen processing such as plasma isolation and creation of aliquots. We use FreezerWorks Summit 2018 sample management software and only authorized and trained BioCORE personnel are allowed to enter sample information and perform sample check in/check out. BioCORE personnel will work closely with researchers to discuss how the BioCORE can best be of service. The BioCORE also has dedicated storage for research specimens derived from the ACH pediatric and neonatal intensive care units (PICU & NICU). Researchers wishing to use the BioBanking service in the BioCORE must submit a formal Application for Services, including a valid Research Ethics Board (REB) approval certificate, for review.

6.1.1 Standard BioBanking

Includes patient & sample database entry, unique sample barcoding, secure -80C freezer storage, unlimited sample transfer activities (sample deposits & withdrawals). This service is charged on a cost-recovery basis, and so costs will depend on the details of the study (# of samples).

6.1.2 Sample Processing & BioBanking

Includes sample processing at the time of new patient/sample acquisition, such as isolation of plasma from whole blood. This includes creation of aliquots of each sample (up to 10 aliquots per sample). This service is charged on a cost-recovery basis, and costs will depend on the details of the study (kinds of samples, # of samples, and # of aliquots).

6.1.3 Temporary Biostorage (< 6 month)

This service is intended to support researchers who may need a temporary location to store research samples before moving them to a final location outside of the BioCORE. Samples will not be barcoded or entered into the sample database. Temporary Biostorage is not guaranteed. Limited -80C freezer space is available for temporary storage of samples (in standard 2" or 3" boxes only). The time limit for temporary storage will be <6 months.

6.2 Arm 2: Bioanalysis service

The BioCORE offers a suite of bioanalysis options for analyzing research specimens. Currently, bioanalysis services include Multi-plex Immunoassays and single-target ELISAs. In the future we hope to offer a non-targeted metabolic profiling service using our state-of-the-art UHPLC Q-TOF Mass Spectrometer. Additionally, we plan to expand the BioCORE to include several more analytical services that will be available to researchers.

6.2.1 Multi-Plex Immunoassays

The BioCORE uses the BioRad® Bio-Plex® 200 multiplex system. Bio-Plex assays are available that measure many biological targets involved in: inflammation, disease, cancer, cell signaling, apoptosis, and more. We offer discounted prices for assay kits through our relationship with Bio-Rad. Please let us know which assays you are interested in and we can obtain a quote on your behalf. For a full list of available Immunoassays please visit: http://www.bio-rad.com/en-ca/category/bio-plex-multiplex-immunoassays?ID=O5BUUA15**.** We offer two options for sample analysis: i) instrument training on the Bio-Plex for those researchers who prefer the 'do-it-yourself' approach, or ii) BioCORE personnel will run your assays for you. Both options are offered on a cost-recovery basis.

6.2.2 Enzyme-Linked ImmunoSorbent Assays (ELISAs)

The ACH BioCORE is pleased to offer a variety of ELISA assay services built on commercially available kits using an in-house multi-label plate reader. We are experienced with performing each of the three common types of ELISA: indirect, sandwich, and competitive. We will perform ELISA assays using the best standards of practice (including sample blinding and randomization) and provide all raw data and assay-specific data analysis. Our EnVision™ multi-label plate reader from PerkinElmer® is capable of measuring absorbance, fluorescence, high sensitivity luminescence, and includes temperature control and many more complex features for more sensitive assays.

6.3 Application for Services

i. Access to the service(s) provided by the ACH BioCORE must be requested by completing and submitting an **Application for Services**, which can be found on our website at: https://www.research4kids.ucalgary.ca/ach-biocore

ii. Submitted applications will be evaluated by members of ACH BioCORE Review Committee.

iii. All studies must have Research Ethics board (REB) Approval for human studies, or Animal Care Committee (ACC) Approval for animal research studies.

iv. Applications will be evaluated based on the following criteria:
   a) Logistics of fulfilling the requested services
   b) Alignment of the research study to the ACH BioCORE priority areas
   c) REB Approval & Research Study Protocol (required for regulatory compliance)

v. BioCORE services are offered on a cost-recovery basis. Costs will depend on the details of your study, including the number and type of samples and which services are desired.

vi. All applications will be reviewed and we will communicate directly with applicants to further discuss how the BioCORE can best serve you.

vii. A Service Invoice will be generated and provided to researchers, and must be paid in full before service(s) will begin. Internal clients can pay for an invoice using a project transfer. External clients will be billed by a University of Calgary ProForma invoice.

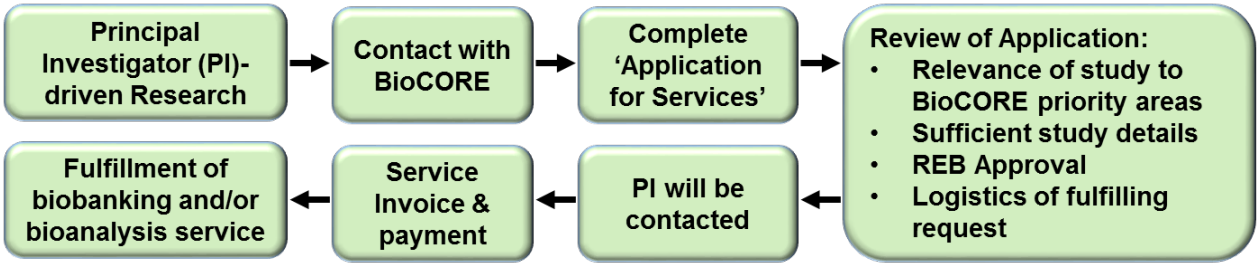
6.4 Service Invoice & Restrictions

After the BioCORE has reviewed the Application for Services, discussions will begin with the PI to understand clearly what is needed by the PI/study team. The costs of each service requested will be determined using cost-recovery calculators and the BioCORE will generate a Service Invoice that clearly states all services, deliverables, and costs. If a biobanking service is requested, clear restrictions will be in place regarding biospecimen handling, sample custody, and sample transfer requests. All requests to store new samples or withdraw samples being stored in the ACH BioCORE must be received at least two (2) business days before samples are dropped off or picked up by the research study team. Please see below for flow chart overviews of the BioCORE service request process and sample management.

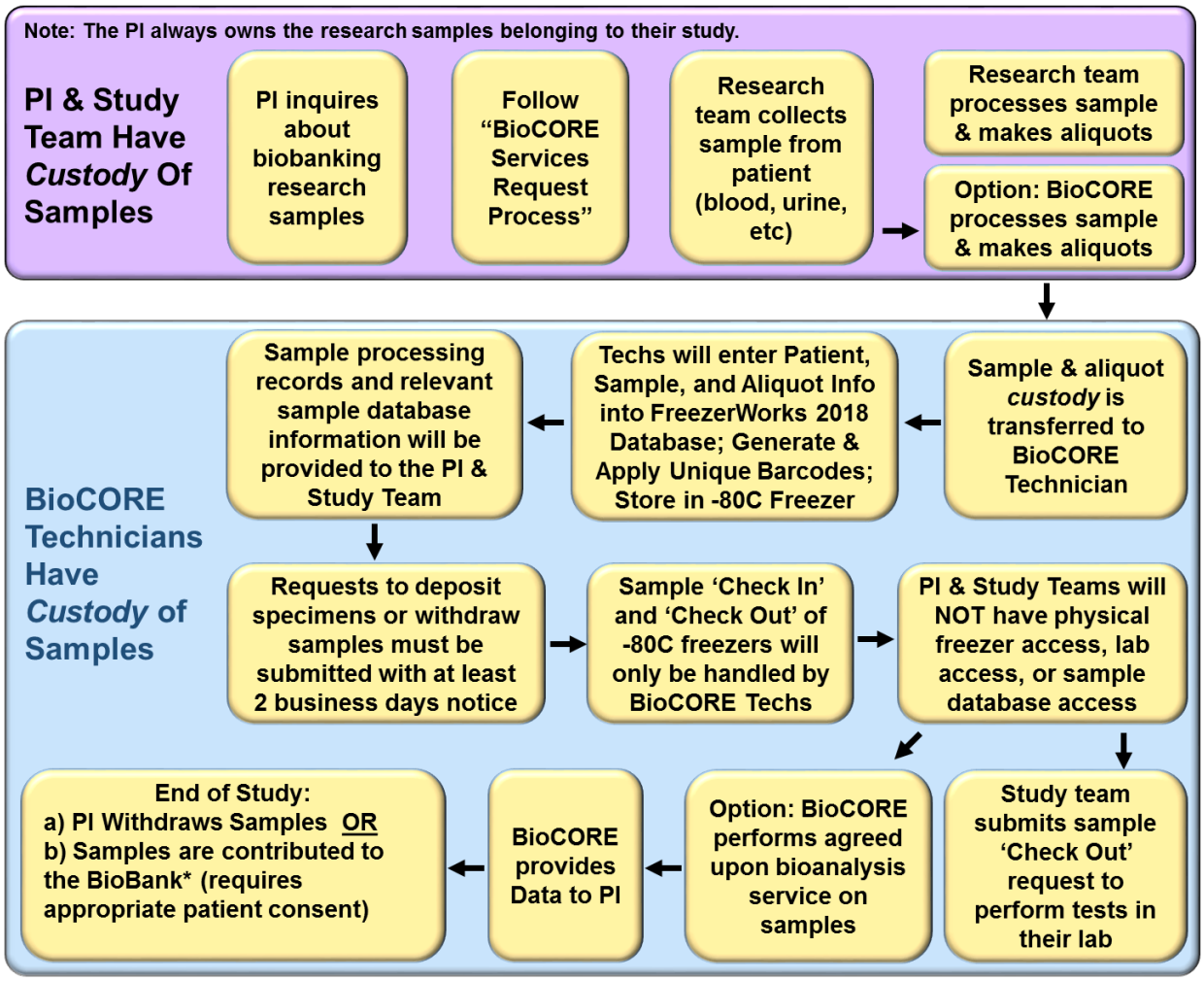
6.5 Cost Structure for Services

The BioCORE will use costs calculators when creating Service Invoices for BioBanking and/or Bioanalysis services for clients. The BioCORE BioBanking cost-recovery calculator is based upon the University of British Columbia (UBC) Office of Biobank Education and Research (OBER) Biospecimen User Fee Calculator [https://biobanking.org/webs/biobankcosting], with some slight modifications to reflect the prospective nature of our biobanking service. The BioCORE has also created a separate cost-recovery calculator for the bioanalysis services offered in the BioCORE. Each of these cost-recovery calculators is designed to account for all associated costs of providing each service. These costs include: equipment costs, software costs, service contracts, technician salary (technician time for each service or task), consumable materials and reagents, and assay kits (bioanalysis only). Depending on the affiliations of the Principal Investigator of the research study, some services or aspects of services may be eligible for subsidized pricing. This will be determined by the BioCORE Review Committee.

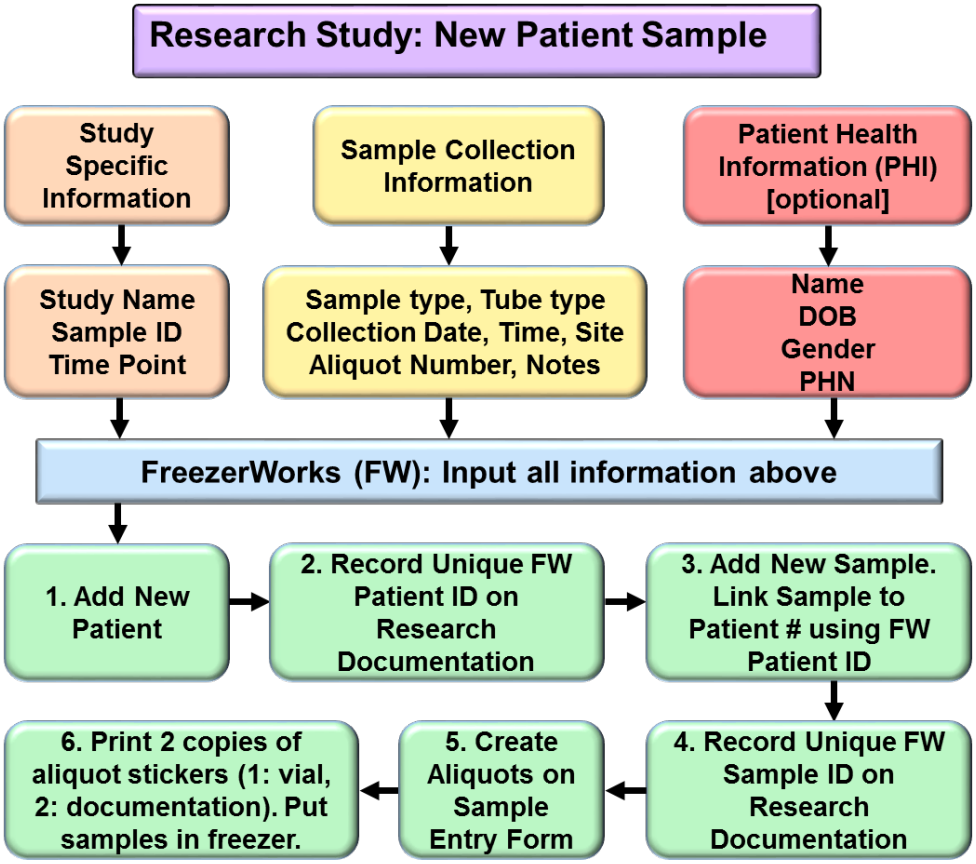
6.6 BioCORE Services Request Process Overview



6.7 BioCORE Sample Management & Restrictions Overview



6.8 New Patient and New Sample Data Entry Overview



7. ACH BioCORE Security Considerations

Category	Description	Risk	Mitigation & Management
Physical Security	-80C freezer is left unlocked	Low	B0-103 lab is badge access only
	-80C freezer is located beside other non-BioCORE freezers	Low	All lab personnel are highly trained and familiar with freezer ownership
	-80C freezer backup space	Low	A new freezer has been ordered
	Computers are not physically secured	Low	All data is password protected and/or stored on secured network drives
	BioCORE visitors in lab space	Low	Visitors must be escorted in the lab and sign a visitors log at each visit
	-80C freezer temperature monitoring	Low	-Freezers are under constant digital monitoring for temperature fluctuations -High temperature triggers a site visit and cascading notification of lab staff -Freezers are manually monitored and temperatures logged daily in the morning and evening by lab personnel
	-80C freezer electricity power	Low	-Freezers are plugged into 230V electrical sockets with backup generator power

			-Each freezer has a built-in 24 hour backup batter
Data Security	Identifying patient information & personal health information (PHI)	Med	-Paper records with patient information are stored in a physically locked cabinet, within a badge-access lab -Only authorized biobank personnel have access
	Patient & sample electronic data management	Low	-FreezerWorks 2018 sample management database software is in use -Only BioCORE Techs have access to patient & sample information -This software uses unique identifiers to distinguish all patients, samples, and aliquots -All PHI entered into FreezerWorks is hidden by default and can only be accessed by BioCORE personnel
	FreezerWorks database backup	Low	Weekly complete database backups are scheduled to automatically download to a secured AHS network drive
	Data transfer	Med	-Data transfer within the BioCORE will be encrypted at the level of each file using AHS email -Data will be de-identified and associated with the minimum amount of information required -Data transfer to PI & research study will be discussed with each PI but must comply with AHS standards of confidentiality & security
	BioCORE digital files	Low	All data is stored on secured AHS network drives, not on local computer drives
	Computer Log In	Low	User log in & authentication is controlled by secure AHS networks
Data Quality	Patient/sample database entry	Low	-BioCORE Standard Operating Procedures (SOPs) have been created to standardize data entry into FreezerWorks (FW) -BioCORE technicians will perform all sample entry -FW data entry lists will include mandatory entry fields, double-entry validation, drop-down lists, strict date and time formatting, and minimal free text entry options
	Patient/sample records	Low	-New patient/sample paper records will be stored in a study-specific binder and locked in a cabinet in -Digital logs of all new sample processing, accessioning, check-in, check-out, modifications, bioanalysis, and data will be stored in excel spreadsheets -Sample 'Check In' and 'Check Out' will be performed using standard Workflows in FreezerWorks
	Regular maintenance and servicing of equipment		-Routine maintenance, washing, calibration, and validation will be performed according to each manufacturer, and records kept -SOPs will be developed and constantly revised to ensure proper maintenance

8. Contact Information for the BioCORE

If you have any questions about the information provided in the policy or information not contained in this policy document, please contact us using the information below.

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