Expanded Concept Brief: The Automated Biospecimen & Data Engine

Core Component of the Clinical Trials Acceleration Platform (CTAP)

1. Strategic Vision: The "Living" Biobank

The traditional biobank is a static archive. For CTAP, we propose a **"Living Biobank"**—an ecosystem where physical samples are continuously updated with real-time health data.

By merging the **University of Alberta's automated cold-chain capabilities** with Alberta's unique single-payer health data assets (Connect Care), we will move beyond simple storage to create a **phenotypically enriched discovery engine**. This facility will not only store samples from clinical trials but also autonomously identify and capture high-value "remnant" samples from the health system, turning medical waste into research gold.

2. Core Operational Pillars (Updated)

Refining the previous objectives with specific innovations from the B-PREPARED proposal.

Pillar A: The "Waste-to-Wonder" Pipeline (Remnant Sample Capture)

- **The Innovation:** Most biobanks rely on expensive, active recruitment. We will implement a **Remnant Sample Interception System**.
- **Mechanism:** Leveraging the provincial Laboratory Information Management System (LIMS), CTAP will identify samples of interest (e.g., from patients with specific rare phenotypes or emerging pathogens) scheduled for destruction after clinical testing.
- **Process:** Instead of incineration, these samples are intercepted, pseudonymized, and automatically routed to the biobank.
- **Benefit:** Rapid accrual of thousands of samples for assay development and control groups without the high cost of recruiting individual patients.

Pillar B: Deep Phenotyping via EMR Integration & AI

- **The Innovation:** A sample is only as valuable as its data. We will eliminate manual data entry errors by linking the biobank directly to the **Connect Care (Epic) EMR**.
- **Mechanism:**
    - **Structured Data:** Automated pull of labs, medications, and vitals via HL7/FHIR standards directly into the biobank LIMS.

    - **Unstructured Data (AI):** utilizing **Natural Language Processing (NLP)** agents (developed by Amii) to curate critical information from unstructured clinician notes (pathology reports, discharge summaries) that usually remain "locked" away.
- **Benefit:** Every vial in the freezer is virtually linked to a complete longitudinal patient history, allowing researchers to query samples based on outcomes that happened *years after* collection.

Pillar C: Dynamic Consent & Patient Partnership

- **The Innovation:** Moving away from broad, static consent to **Dynamic Consent Portals**.
- **Mechanism:** A secure, patient-facing digital portal (integrated with MyHealth Records) where participants can track how their samples are being used, receive updates on research outcomes, and manage their consent preferences in real-time.
- **Benefit:** Increases public trust and retention in long-term studies, ensuring CTAP meets the highest ethical standards for Indigenous and community partnership.

3. Infrastructure & Equipment Requirements (The "Ask")

A. The Physical Hardware (Automation & Robotics)

- **Automated Storage & Retrieval Systems (ASRS):**
    - *Request:* High-density, automated -80°C stores and vapour-phase LN2 systems.
    - *Justification:* "To consolidate the energy footprint of 20+ decentralized freezers into a single, secure, robotically managed core that eliminates thermal cycling events."
- **Liquid Handling & Aliquoting Robotics:**
    - *Request:* Hamilton/Tecan class liquid handlers with decapping and reformatting capabilities.
    - *Justification:* "To standardize sample processing for 'Remnant Sample' intake, converting non-standard clinical tubes into high-density storage formats (96-well Micronic) without human intervention."

B. The Digital Backbone (Cloud & Security)

- **Federated Data Infrastructure:**
    - *Request:* Secure cloud architecture (AWS-aligned) to host the **CBSR BioBank software**.
    - *Justification:* "To enable a federated model where samples physical location is central, but their *data* is discoverable by researchers globally, modeled after the UK Biobank's cloud architecture."
- **AI Compute Integration:**
    - *Request:* Edge computing nodes for on-site data processing.

    - *Justification:* "To run NLP algorithms on sensitive health data locally (within the secure firewall) before metadata is pushed to the cloud, ensuring privacy compliance."

C. Biomanufacturing Quality Control (The Industry Link)

- **Reference Material Generation:**
    - *Concept:* The biobank will serve as the "Quality Control Library" for the **Alberta Cell Therapy Manufacturing (ACTM)** facility.
    - *Usage:* Storing well-characterized "Gold Standard" human tissues and cells to serve as benchmarks for GMP manufacturing runs.
    - *Justification:* "Ensuring that 'Made-in-Alberta' cell therapies meet rigorous regulatory standards by comparing them against a consistent, cryopreserved reference library."

4. Summary for the Grant Proposal

"CTAP proposes to build Canada's first **Deeply Phenotyped, Automated Biorepository**. By fusing industrial-scale robotics with Alberta's integrated EMR, we will solve the three greatest challenges in translational science:

1. **Access:** Automating the capture of 'remnant' clinical samples to build massive control cohorts.
2. **Context:** Using AI to structure 'dark data' from clinical notes, giving every sample a rich medical history.
3. **Quality:** Removing human variability through robotics to support precise biomanufacturing and genomics.

This is not a storage facility; it is a **biological search engine** for the next generation of clinical trials."