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Technological and Administrative Factors Implementing a Virtual Human Biospecimen Repository

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THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER
LIBRARY AND INFORMATICS CENTER

Overview

Informatics tools make it possible for researchers (both intra- and inter-institutionally) to locate tissue needed for research faster and more reliably. We are developing a Virtual Human Biospecimen Repository (VHBR) to both inventory and link all human biospecimens with clinical and genomics data to optimize their value for research, while satisfying all privacy and human subjects protections regulations.

Human Tissue Oversight Committee

The HTOC has authority over the collection, reporting, and distribution of tissues held in the repository. The HTOC meets quarterly to review and modify policy, oversee budgets, choose and assess the repository's director.

The Scientific Review Committee

The SRC mediates the use of unique, rare or nearly exhausted tissue samples using the following evaluation criteria:

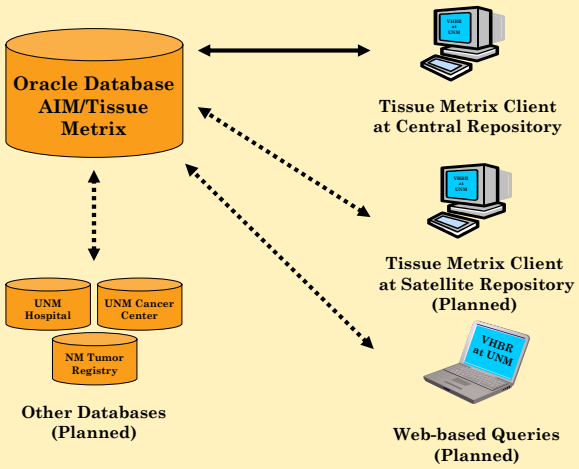
- Scientific Merit
- Demonstrated expertise of the investigator/research team
- Demonstrated availability of sufficient funding and physical resources
- Risk to study subjects versus the possible benefits to be derived

Human Research Review Committee

The HRRC (UNM's IRB) must review and approve all proposals using tissue from the tissue repository.

Tissue Procurement Process

System Architecture



Administrative Tissue Categories

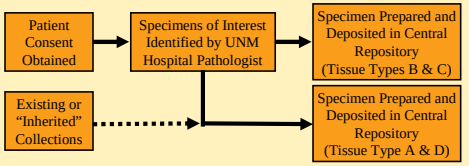
Type A. Excess tissue alternatively prepared for possible future diagnostic purposes. (No IRB oversight or consent status as tissue prepared for diagnostic studies only.)

Type B. Excess tissue alternatively prepared for a known HRRC-approved active research project with HRRC-approved consent status.

Type C. Excess tissue alternatively prepared for unknown future research project with Tissue Repository consent of patient.

Type D. Excess tissue alternatively prepared for unknown future research project with waiver of informed consent, waiver of HIPAA authorization, Tissue Repository as honest broker for identifiers and dispensed as de-identified samples.

Specimen Acquisition Process



Functional Requirements

Critical to the success of the virtual repository is strong informatics support. The HTOC's Technical Subcommittee, the body that oversees the technical administration of the repository, identified the following functionalities as key components of the informatics tool needed:

- Support for a 4-types of patient consent.
- Strong audit trail capabilities
- Highly configurable user privileges to support user types that allow both effective administration and highly restricted access to support de-identified-only queries.
- Data dictionary support tools, including specific support for SNOMED and LOINC.
- HL-7 Interface/external database linking capability
- Strong database query functionality
- Clinical/genomics data storage capability that is highly configurable.

Current Data

Currently there are 1300 samples stored in the VHBR with 15 more being added per month on average. The VHBR contains samples "inherited" from three other collections at UNM. We are currently analyzing data structures and requirements of five additional satellite collections at UNM identified for future accession into the VHBR.