CTSI Biorepository

The UF CTSI is supported in part by NIH/NCATS Clinical and Translational Science Award to the University of Florida UL1 TR001427.
UF Biorepository Organizational Chart

Regulatory Manager:
- IRB protocol submission/ Revisions
- Staff training
- Personnel document control
- Consenting
- Regulatory documentation

Client Coordinator:
- Interfaces with legal and regulatory
- Process verification
- Directs & tracks specimen requests/distribution

Director
Michael Clare-Salzler, MD

Assistant Director

REGULATORY SECTION
- Regulatory Manager/Consenter

LABORATORY SECTION
- Lab Tech/OR Runner
- Lab Tech/OR Runner
- Lab Tech/OR Runner

Lab Tech/OR Runner:
- Specimen processesing (blood/fluid/tissue)
- Specimen reconciliation
- Storage tracking and retrieval
- Transport tissue from OR
- Dissect and process specimens

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High-Quality Infrastructure

• College of American Pathologists (CAP) Accreditation:
  o Accredited in 2012; Re-accreditation On-Site Inspections in 2015, 2018

• “Best Practices Guidelines” of the International Biological and Environmental Repositories (ISBER) and the Biorepositories and Biospecimens Research Branch (BBRB)

• OnCore BSM database
  o OnCore tissue inventory linked to IDR and de-identified EPIC patient database to enable cohort-specimen pairing
  o Contains demographics, extensive specimen annotations, pathology reports
High-Quality Infrastructure

• **Quality Assurance Program**
  - SOPs for all Biorepository operations
  - Highly trained staff; Recurrent QA monitoring
  - Annual internal audit; CAP external audit every 3 years
  - Monitoring systems with Emergency Response Plan
  - Backup systems on all freezers
  - OR Runner Program – patient to storages → 30 min goal
  - Pathologist confirmation of tissue type, cancer + % tumor

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Service Lines

• **Institutional Biospecimen Library** (~32,000 currently available)
  - Fresh-frozen tissue: Tumor and matching normal from same patient, same organ
  - Mirror image FFPE blocks of fresh-frozen tissue samples
    - Tumor and matching normal from same patient, same organ
  - Corresponding blood/blood derivatives: Plasma, Serum, Buffy Coat, whole blood

• **PI-Initiated Storage Services**
  - Exclusive specimen bank created specifically for PI or program
  - Extensive range of storage options, from ambient to LN2
  - CO2 Backed-up freezers with independent 24/7 SensaPhone alarm system and REES virtual monitoring systems
  - Individualized SOP collection, processing, storage and distribution

• **Clinical Trials Support Services**
  - Custom kit creation (study specific)
  - Specimens/kit distribution and shipping, sample receipt, reconciliation and storage
  - Multi-Site management and support

• **PI-Directed Studies**
  - Verify regulatory aspects of the PI research study
  - Limit access to the (Surg-Path) grossing room
  - Function as “gatekeeper” for IRB/Pathology

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Productivity Measures

- Institutional Biospecimen Library
  - Specimen procurement clients:
    - Internal and External

- PI-Initiated Storage Services
  - Specimen storage/processing clients:
    - Internal

- Clinical Trials Support Services
  - Served as the specimen storage repository for the "Lifestyle Interventions and Independence for Elders" (LIFE) Study, a Phase 3 multi-center randomized controlled trial involving 10 different sites across the U.S. consisting of receipt, reconciliation, storage and distribution of more than 185,000 specimens.
  - Serves as the specimen procurement, management and storage repository for the "University of Florida’s CaRE2, Health Equity Center Project", a National Cancer Institute five-year, $16 million grant establishing a cancer health equity center at the University of Florida and partner institutions including Florida A&M University and the University of Southern California.

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Productivity Measures, cont.

• **Clinical Trials Support Services**
  - Serves as the comprehensive trial management repository for the "**Hepatitis C Therapeutic Registry and Research Network** (HCT-TARGET) Consortium" comprising more than 73 sites across the U.S. The services provided include the building of custom sample collection kits, specimen receipt and reconciliation, specimen storage and distribution, and multi-site management and support.
  - Serves as the specimen management and storage repository for the University of Florida’s "**Sepsis and Critical Illness Research Center**", an NIH-funded P50 center studying the long-term outcomes in patients treated for sepsis in the surgical and trauma intensive care units at UF Health.
  - Serves as the UF site’s specimen processing, management and storage repository for the "**Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer**" program.
  - Provided Letters of Support, Biorepository Grant Language/ Budgets, CTSI Vouchers and Pilot Grant support, Consultations to over 300 UF research faculty since 2012

• **PI-Directed Studies**
  - Verify regulatory aspects of the PI/ study team’s research study
  - Limit access to the (Surg-Path) grossing rooms
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Available Tissue Specimens
Cancer & Matching Normal

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Questions?

Visit our website at https://www.ctsi.ufl.edu/research/laboratory-services/ctsi-biorepository-2/