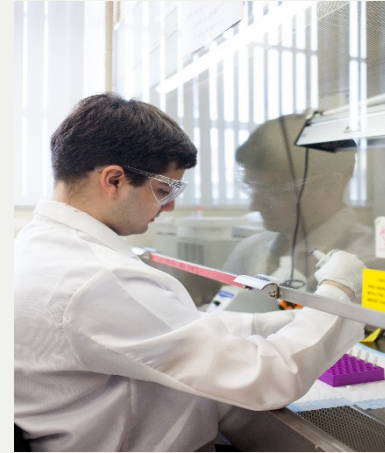


CTSI Biorepository



UF Biorepository Organizational Chart

Regulatory Manager:

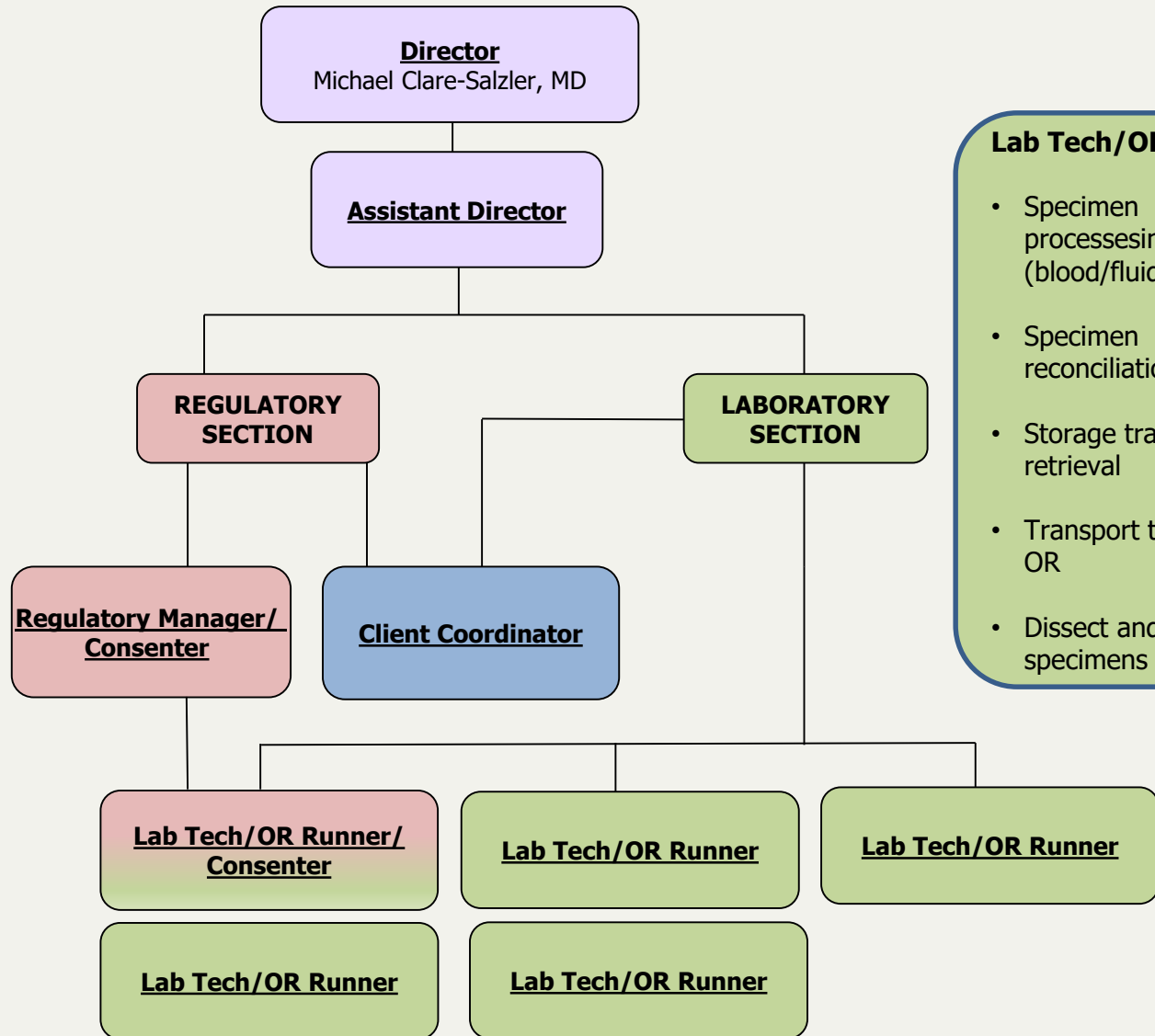
- IRB protocol submission/ Revisions
- Staff training
- Personnel document control
- Consenting
- Regulatory documentation

Client Coordinator:

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

Lab Tech/OR Runner:

- Specimen processing (blood/fluid/ tissue)
- Specimen reconciliation
- Storage tracking and retrieval
- Transport tissue from OR
- Dissect and process specimens



High-Quality Infrastructure

- **College of American Pathologists (CAP) Accreditation:**
 - 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**
 - OnCore tissue inventory linked to IDR and de-identified EPIC patient database to enable cohort-specimen pairing
 - 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

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

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.

Productivity Measures, cont.

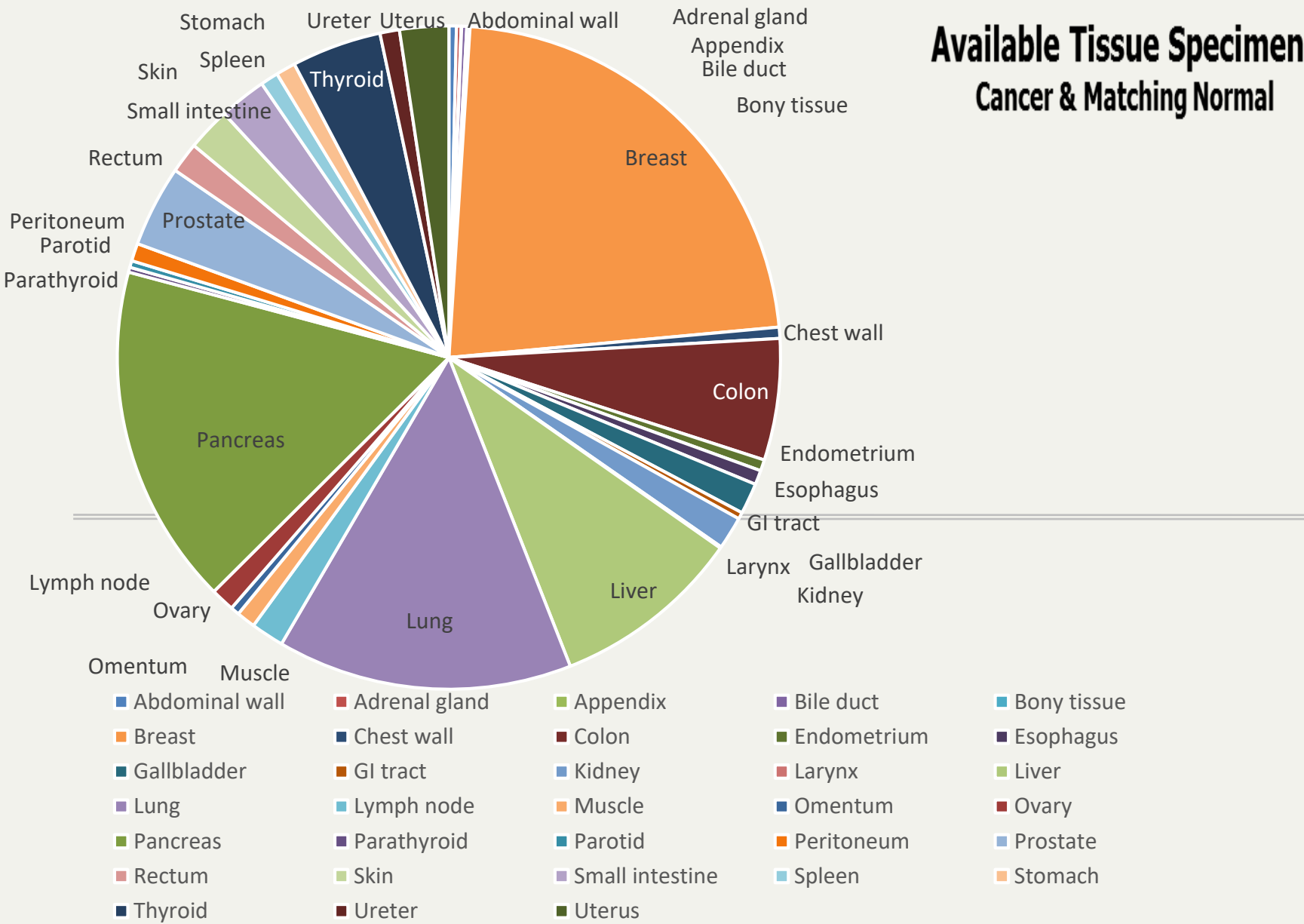
- **Clinical Trials Support Services**

- 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
- Function as "gatekeeper" for IRB/ Pathology

Available Tissue Specimens Cancer & Matching Normal



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

