



Acquisition of Normal Tissues for Research

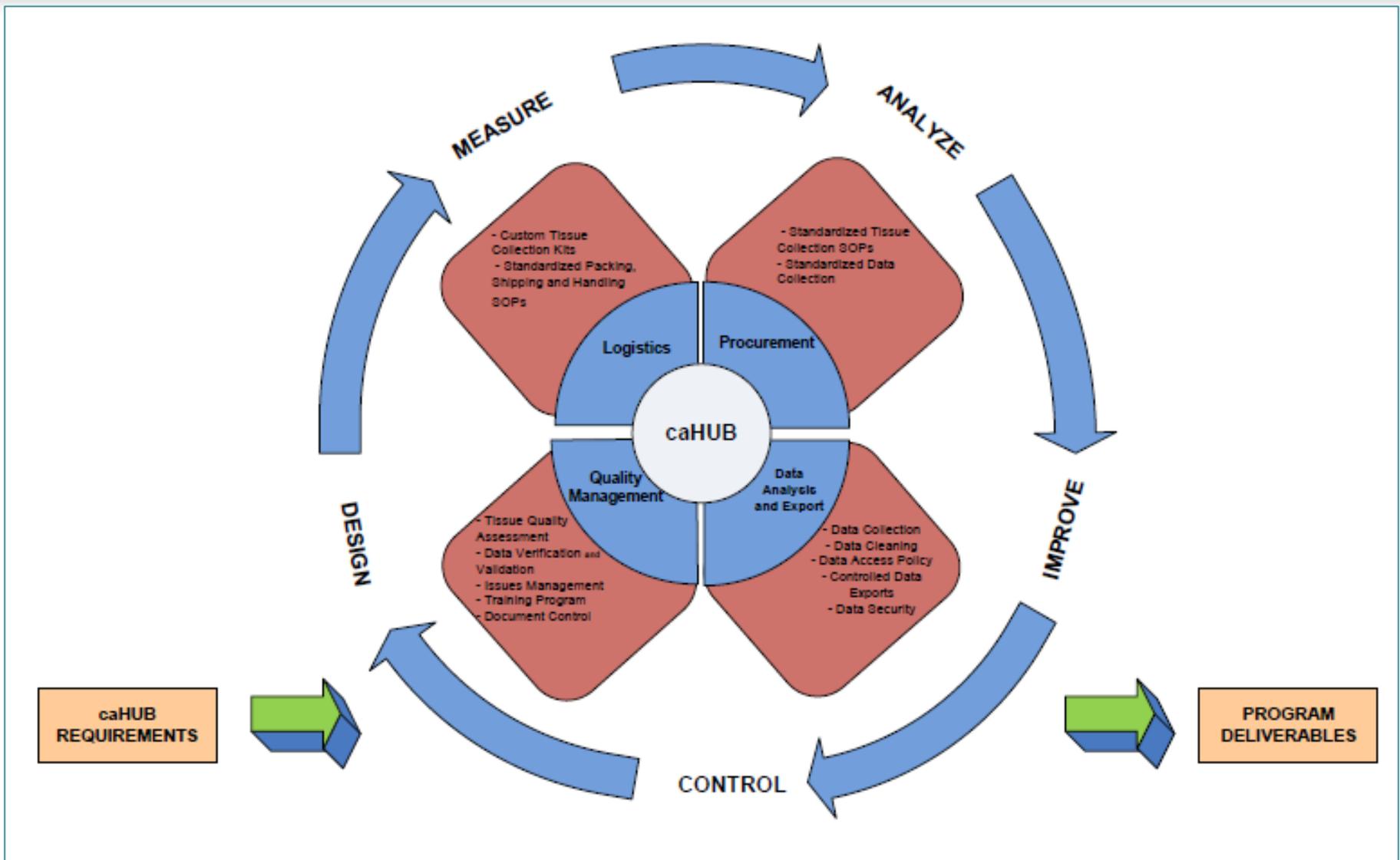
*GTEx and caHUB
Status Report
BRN Symposium, February 2012*

*Jim Vaught
Deputy Director, Office of Biorepositories & Biospecimen Research*

caHUB Goals to Support GTEx Pilot Collections

- **Engage by Competitive Contract**
 - Specialized Biospecimen Source Sites
 - Specialized Comprehensive Biospecimen Resource
- **Secure Source Materials Contract**
 - Indefinite Quantity Supply contract in place with Qiagen (PAXGene™)
- **Build**
 - Quality Management Program
 - Comprehensive Data Resource
 - Training/Auditing Program
 - Pathology Review Structure
- **Design**
 - Ethical and Regulatory Affairs Considerations
 - Data Management Plan and Data Flow
 - Biospecimen Management Plan
 - Collection Logistics
 - Full Chain of Custody System

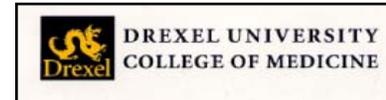
caHUB and GTEx Operations



Contracts Awarded to Biospecimen Source Sites

National Disease Research Interchange (NDRI)

- Organ, Tissue and Rapid Autopsy Referrals
- Surgical Collections
- ELSI Consent Sub-study



Roswell Park Cancer Institute & Upstate New York Transplant Services (UNYTS)

- Postmortem Collections



Science Care, Inc.

- Postmortem Collections



caHUB Biospecimen and Data Infrastructure for GTEx Collection: Operational Complexity

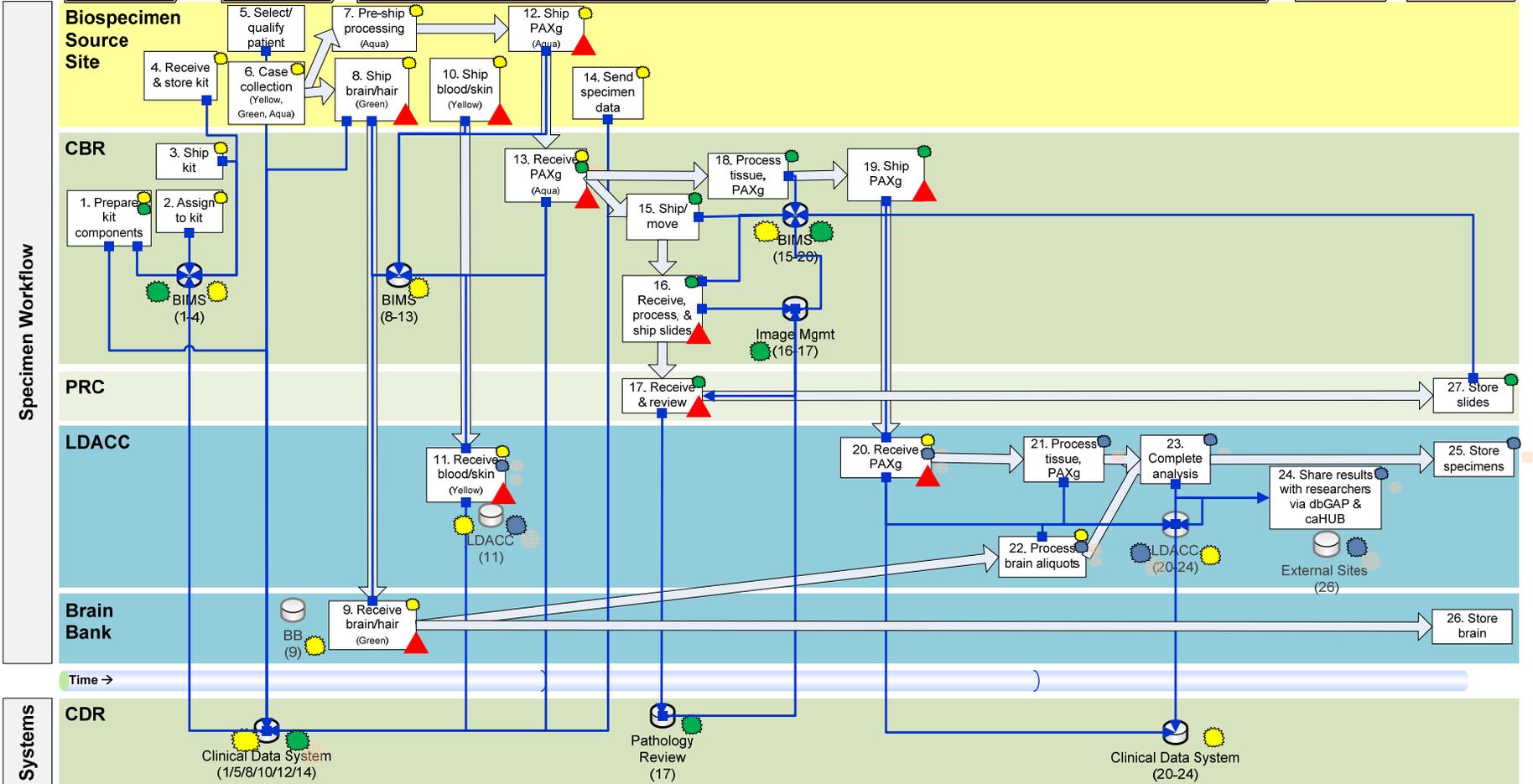
GTEx Biospecimen & Data Workflow

V3.2 – 5/13/2011

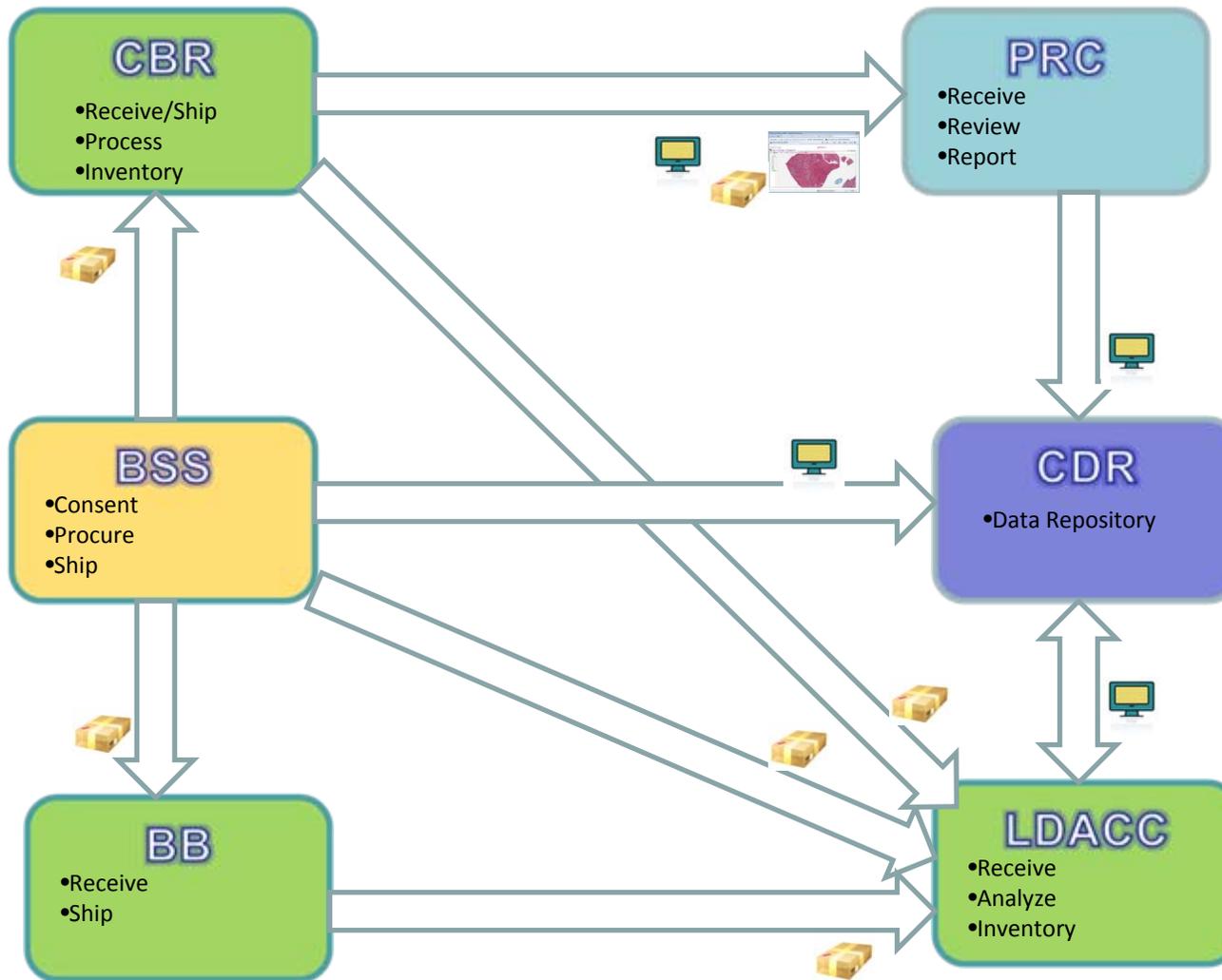
Sample ID + Sequence ID = **Specimen ID** (Yellow)
 HUB Case ID + Sequence ID = **HUB ID** (Green)
 LDACC ID = **LDACC ID** (Blue)

Examples
 GTEx-000002-0101
 GTEx-DF3478EF-0101
 ??????

Chain of Custody Form **▲**
 Specimen flow **→**
 Data flow **←**



caHUB Biospecimen and Data Operations Simplified



Legend:

CBR: Comprehensive Biospecimen Resource

BSS: Biospecimen Source Site

BB: University of Miami Brain Bank

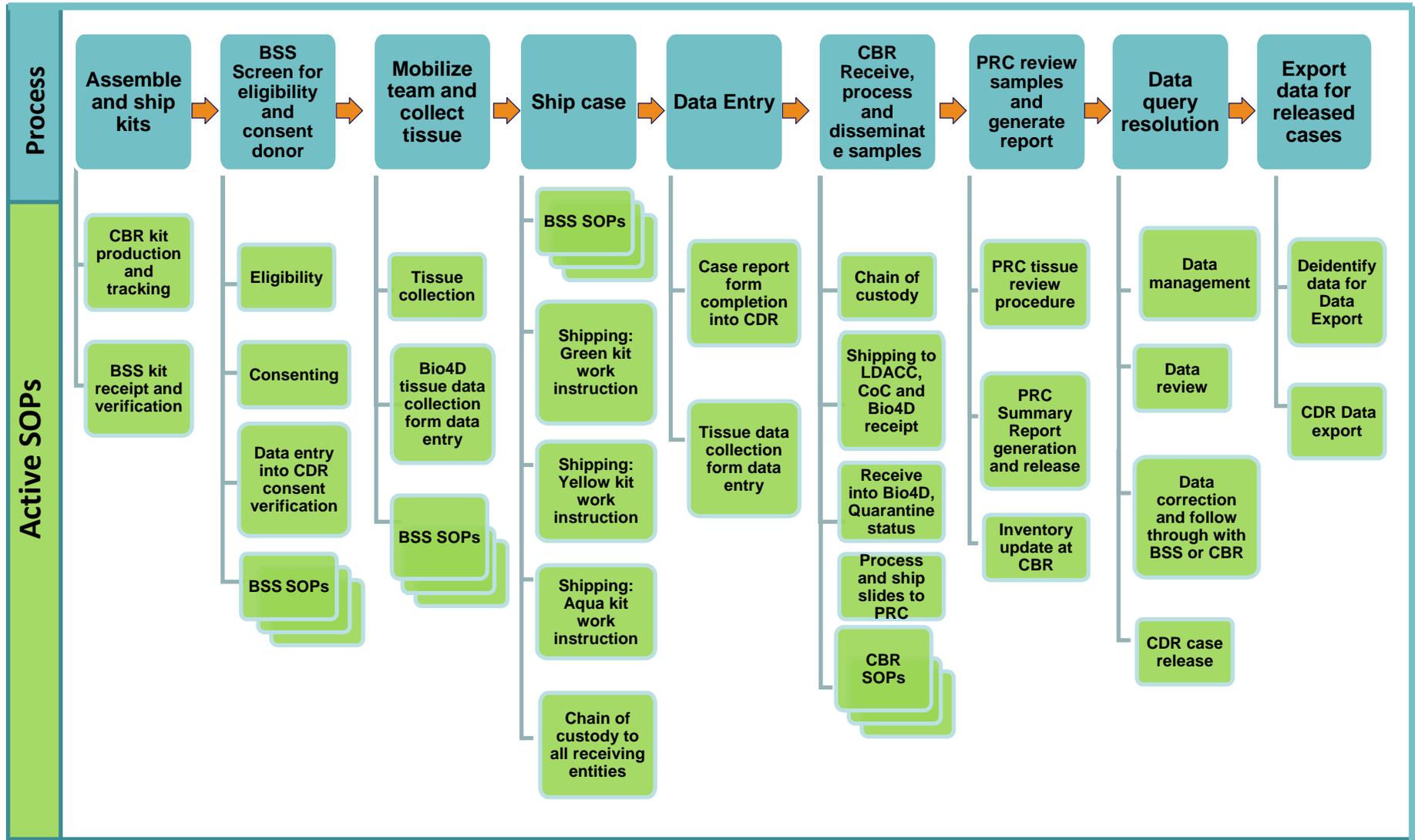
PRC: Pathology Resource Center

CDR: Comprehensive Data Resource

LDACC: Laboratory, Data, Analysis and Coordination Center

GTEEx Operational Process Flow and Related SOPs

Over 150 GTEEx Specific SOPs in use



Uniformity and Adherence through Controlled SOP Development and Implementation

- **Customization**

- SOPs customized to needs of postmortem, tissue and organ collections to promote standardization across sites
- Leads to consistency in BSS collection metrics

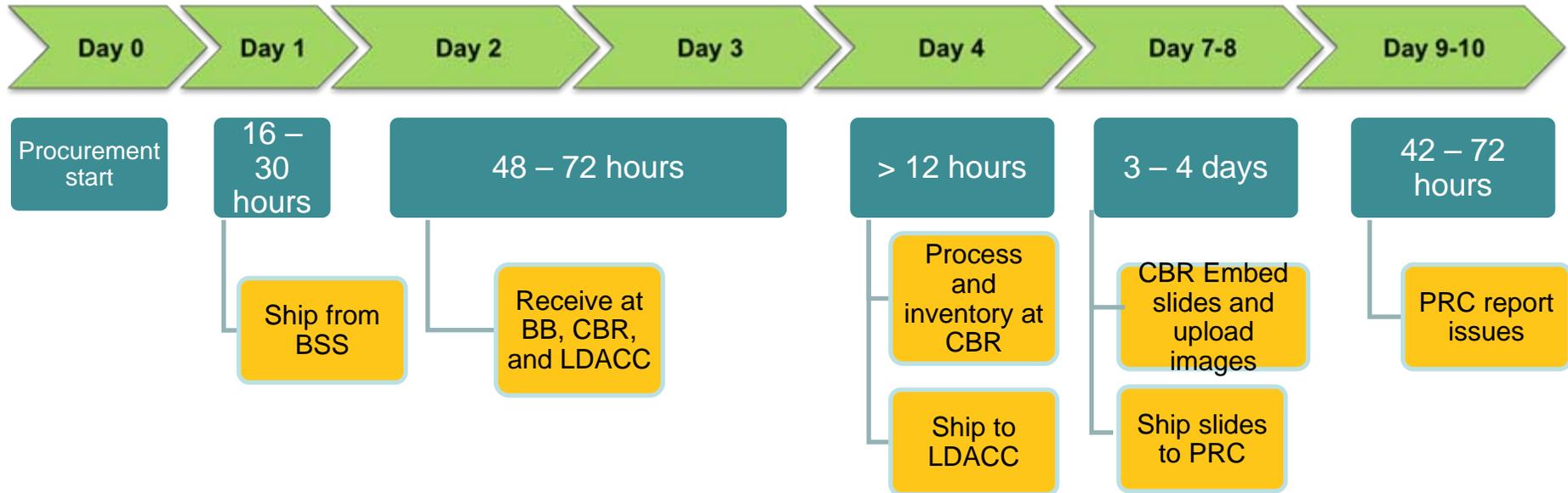
- **Collaboration**

- Feedback from project partners essential to synergize project needs and local operations
- Promotes adherence to policies and procedures

- **Contribution**

- Project goal for SOPs to be available for public use and will be a major contribution to the research community

Timeline from Donor Collection to Pathology Review

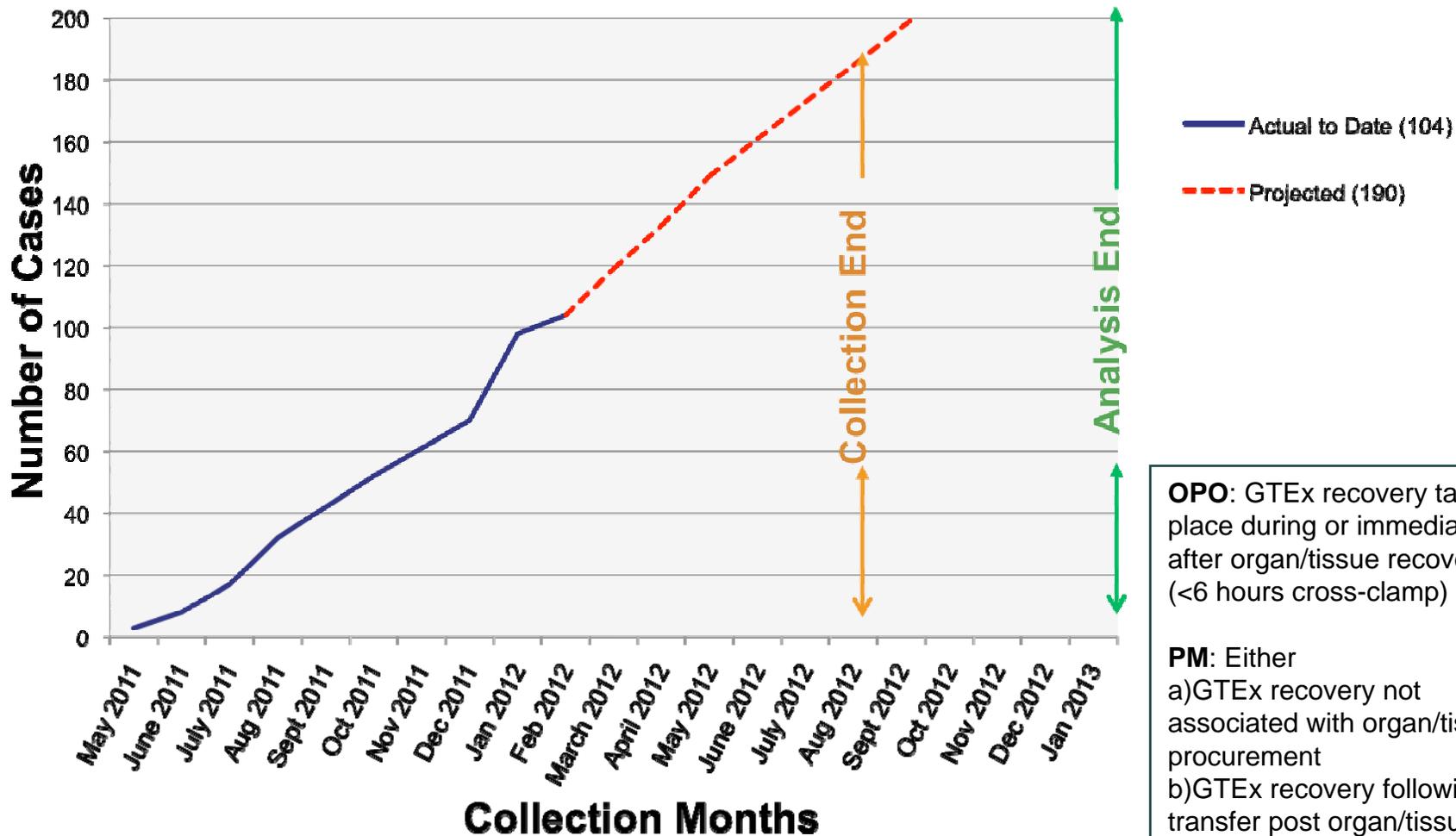


- Shipment of specimens within an average of 24 hours of start of collection
- CBR processing and shipment to the LDACC occurs within an average of 6 hours upon receipt
- CBR prepare and ship slides to the PRC within 72 hours

Time from Collection to Pathology Review averages 2 weeks!

Donor Enrollment

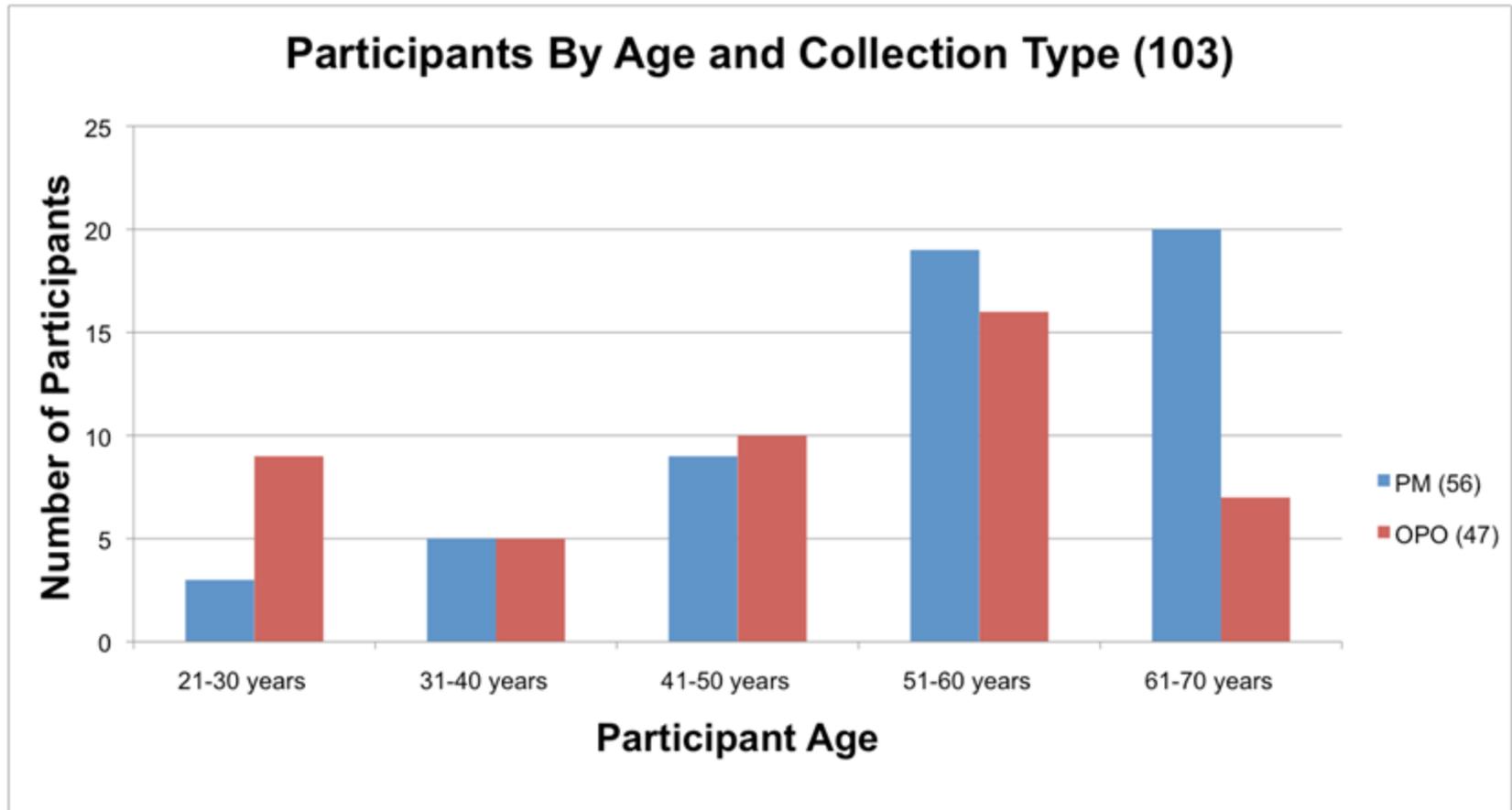
Postmortem/OPO: On Target to Meet Pilot Goal



OPO: GTEX recovery takes place during or immediately after organ/tissue recovery (<6 hours cross-clamp)

PM: Either
a) GTEX recovery not associated with organ/tissue procurement
b) GTEX recovery following transfer post organ/tissue donation (**delay** exists from cross-clamp and GTEX collection)

Enrollment by Age and Enrollment Type



Enrollment by Race and Ethnicity

Race	Ethnicity N (%)			Total N (%)
	Not Hispanic or Latino	Hispanic or Latino	Not reported/Unknown	
Caucasian	44 48%	1 1%	46 51%	91
African American	8 80%	0 0%	2 20%	10
Native Hawaiian	0 0%	0 0%	0 0%	0
Asian	1 50%	0 0%	1 50%	2
Total	53 51%	1 1%	49 48%	103

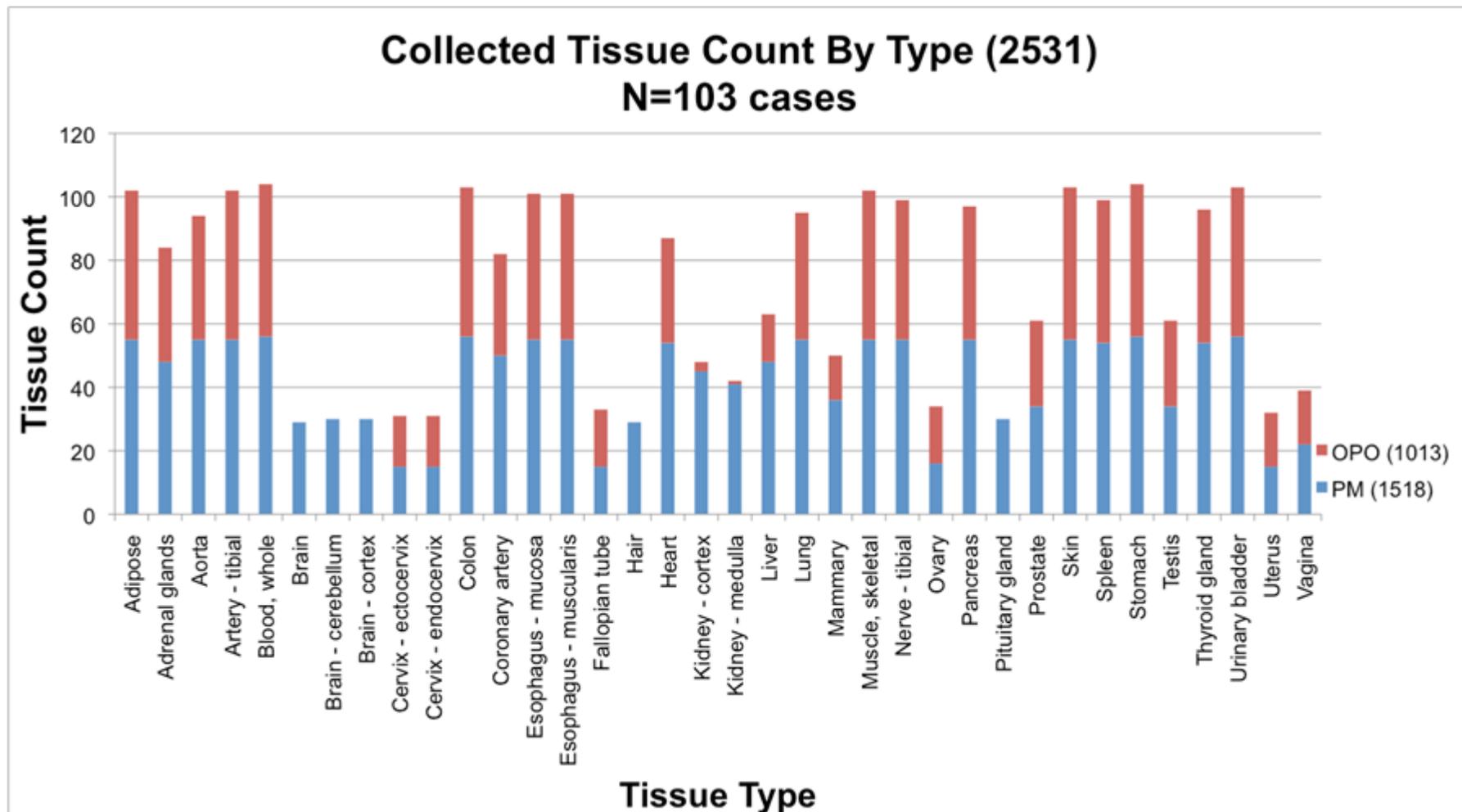
Immediate Reported Cause of Death (COD)

Most Frequent COD

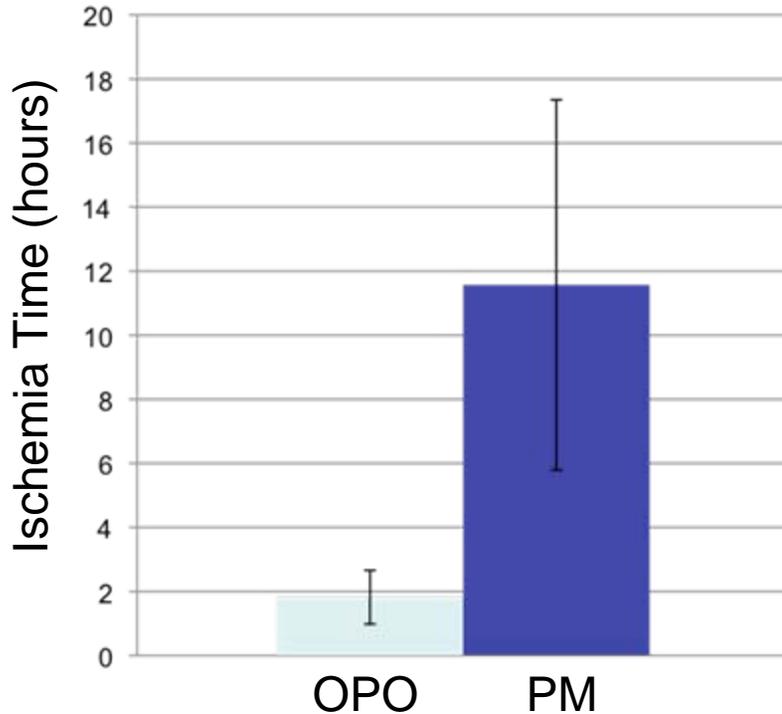
- Traumatic (26% of total donors to date)
 - Head trauma
 - Suicide
- Non-Traumatic (74% of total donors to date)
 - Cerebrovascular accident
 - Cardiovascular incident
 - Anoxia (NOS)
 - Renal, liver

Biospecimen Collection Data

Over 1400 Tissues Collected to Date
Greater than 5000 Aliquots

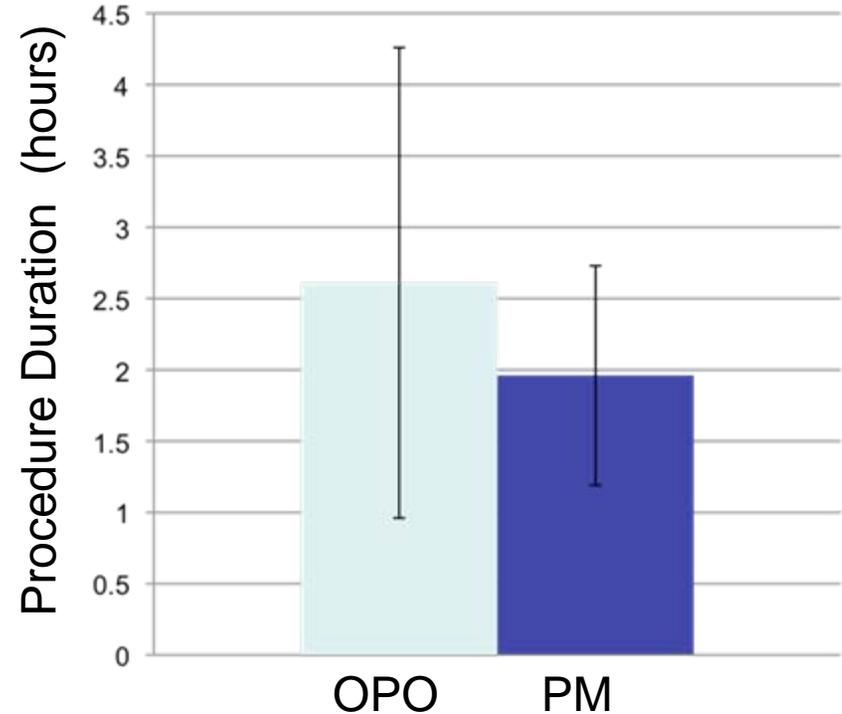


Average Ischemic Time (PMI) and Average Procedure Duration (n=103)



Ischemic Time OPO = time of first specimen in fixative minus clamp time

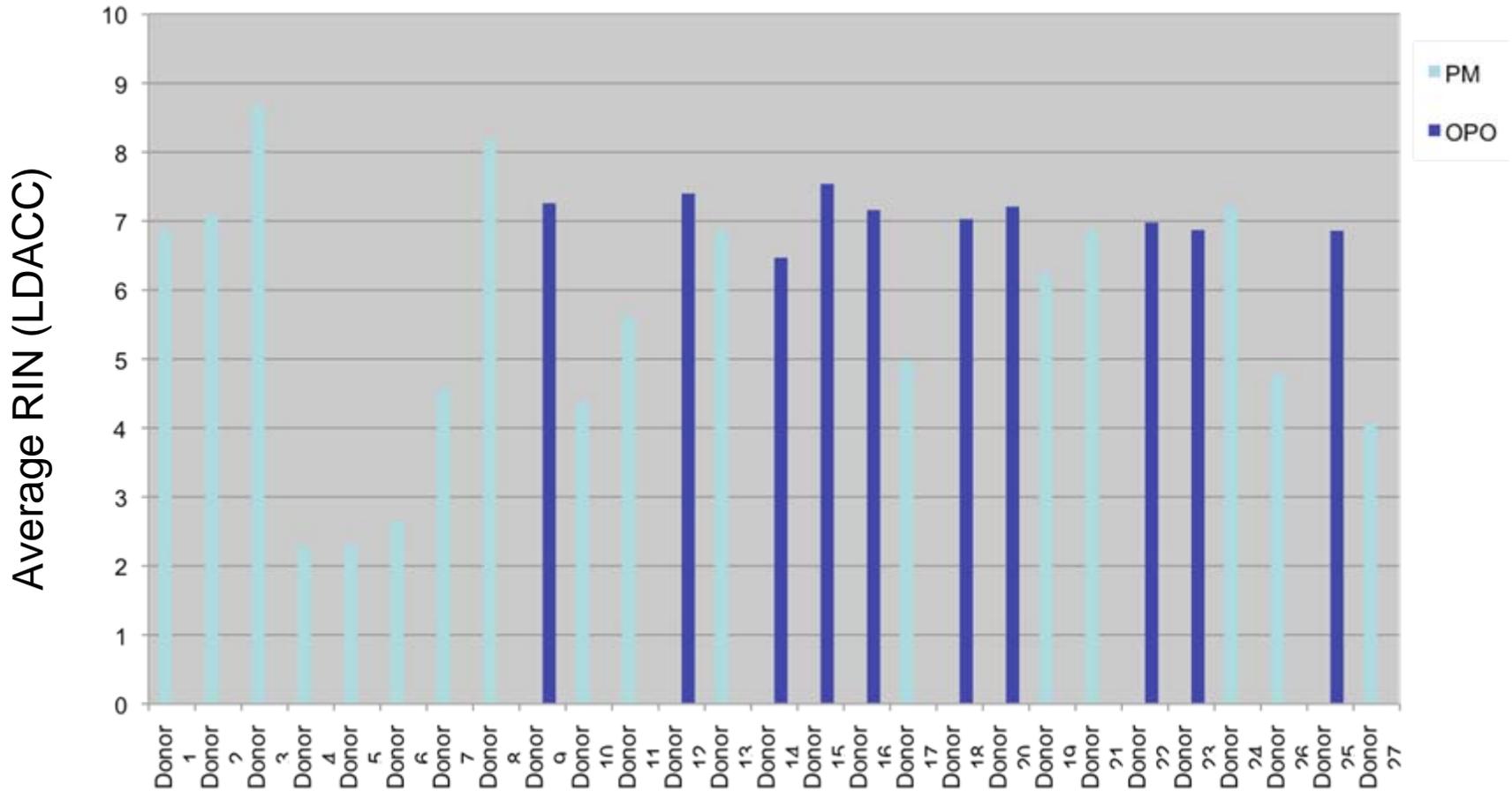
Ischemic Time PM = time of first specimen in fixative minus time of death



Procedure Duration = time of last specimen into fixative minus time of first specimen into fixative

Note: OPO cases often have longer procedure duration as the first specimen is often obtained *during* organ procurement process, with the remainder of the case being conducted *post* organ donation process.

Average RIN by Donor Reported by LDACC (N=27)



caHUB GTEx Growth & Scale-Up Considerations

Additional Aims for the Pilot Phase

- Expand automated data validation
- Complete development of automated data import and export to partners
- Expand analysis of process variables impacting biospecimen quality

Scaling to meet post-pilot project needs

- Increasing throughput for biospecimen procurement
- Optimizing data collection
- Evaluating tissue type targets
- Increasing throughput for processing and inventory control
- Developing automated process and data quality validation
- Implementing expanded quality control measures and metrics

Summary

- **caHUB is:**
 - Providing a novel infrastructure for standardized biospecimen and data collection
 - Tackling a challenging biospecimen procurement network
 - Meeting scientific demands of GTEx with fit-for-purpose biospecimens
 - Delivering on schedule and within budget
 - Generating metrics through continuous evaluation
 - Planning for the future!

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