

BIOS

UCSF Biospecimen Program



Biospecimen Acquisition



**Biospecimen Processing
& Quality Control**



**Biospecimen
Management Software**

BIOS Advisory Committee Retreat

Jan 17, 2019

Purpose

Help shape a sustainable future for the BIOS program by defining the needed infrastructure to support the biospecimen lifecycle at UCSF, and strategizing on how to meet those needs

Goals

- Understand the current state of biospecimen lifecycle infrastructure at UCSF and how BIOS fits into this infrastructure
- Shape the vision for what the future should look like; advise on which parts of that future should be within the scope of the BIOS program and which parts are in other programs.
- Identify governance and sustainability measures to ensure the optimal deployment, advocacy and use of BIOS infrastructure

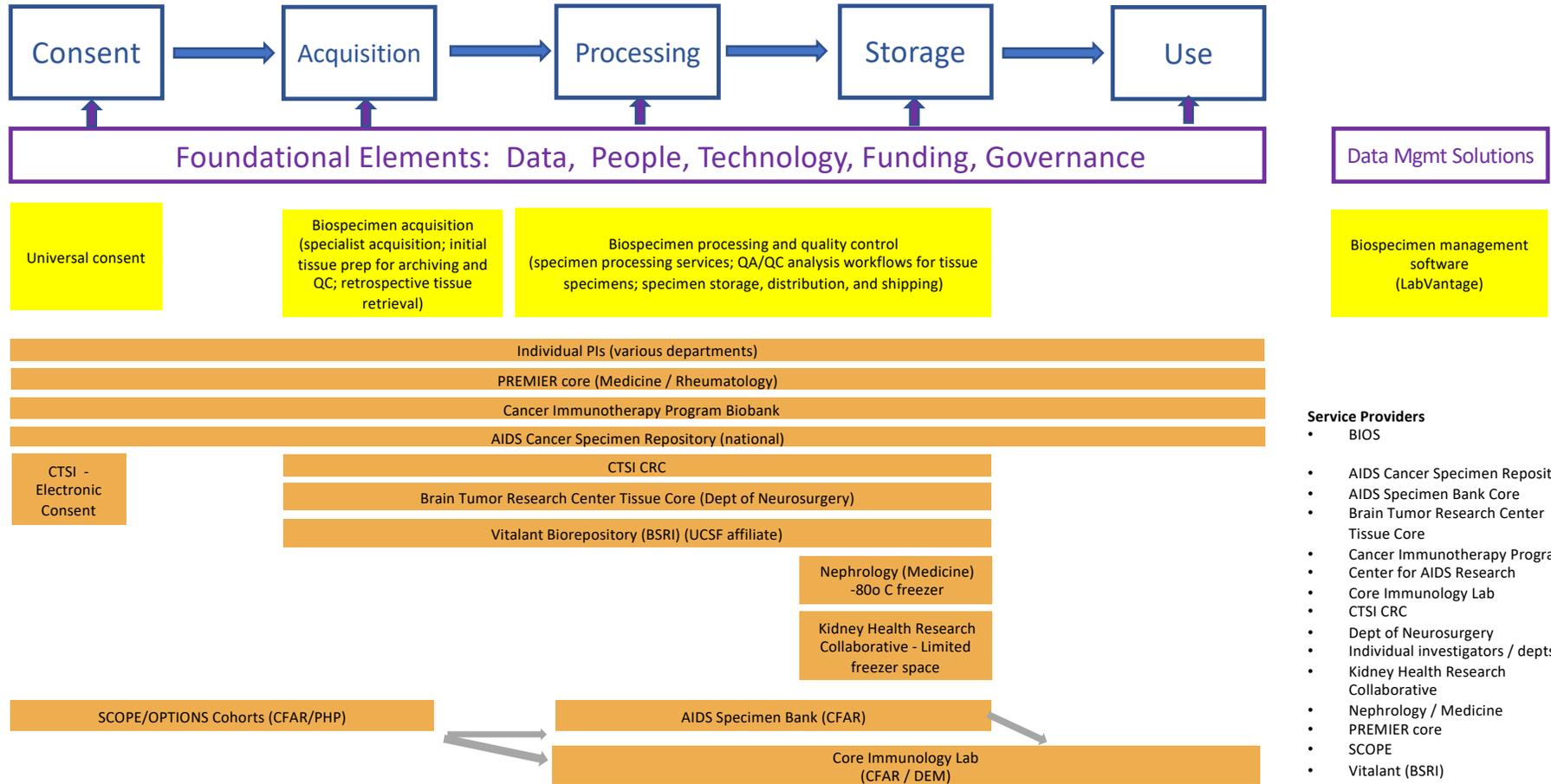
The committee hard at work



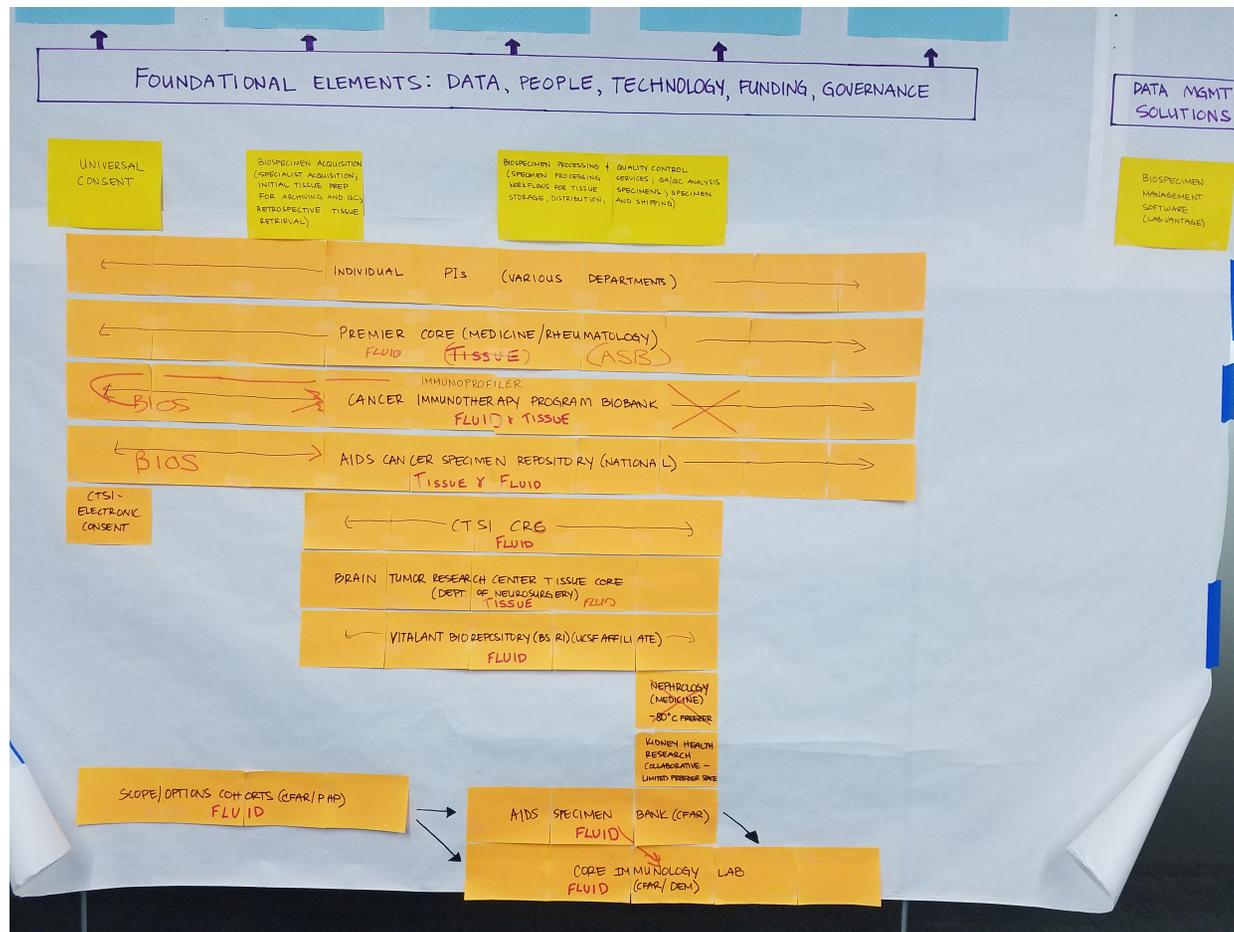
Before retreat

Human Biospecimen Lifecycle Current State

Legend:
Yellow: BIOS program infrastructure available
Orange: Other infrastructure available outside BIOS



Current State – updated during retreat



Current State – reactions / reflections

Our Culture today

- Culture of distrust – people want to do their own (people trust what they do themselves)
- Complexity of collaborations, interactions
- Sounds like “OE” – not trusted / admin hassle
- Surgeons more than others are used to having to support compliance
- Need “carrot” in addition to “stick”
- Unjustified amount of variability and opaqueness
- These challenges are not limited to biobanking

BIOS Services Guiding principles

- Create something young PIs can initially use to get started when they don’t have \$\$
- Some divisions / departments have resources; others don’t. Renovations can cause rapid impacts.
- Multi-campus logistics limit feasibility of centralization (need compromise, and need to identify components where you can’t compromise)
- Create a supportive environment, not punitive
- Centralization is easier than standardization
- So far haven’t talked about overall governance for biospecimens; there is centralized infrastructure, but users have their own governance

Why change from today

- Developed many things because there wasn’t anything central but now there is
- Opportunity left on the table – private sector is going to “eat our lunch” (e.g., 23&Me)
- Clinical labs collect thousands of samples – need processing improvements

Gaps today

- Need adequate safe storage; don’t currently have it consistently
- Co-Labs: doing its own processing, no storage space

Inconsistent Institutional Support

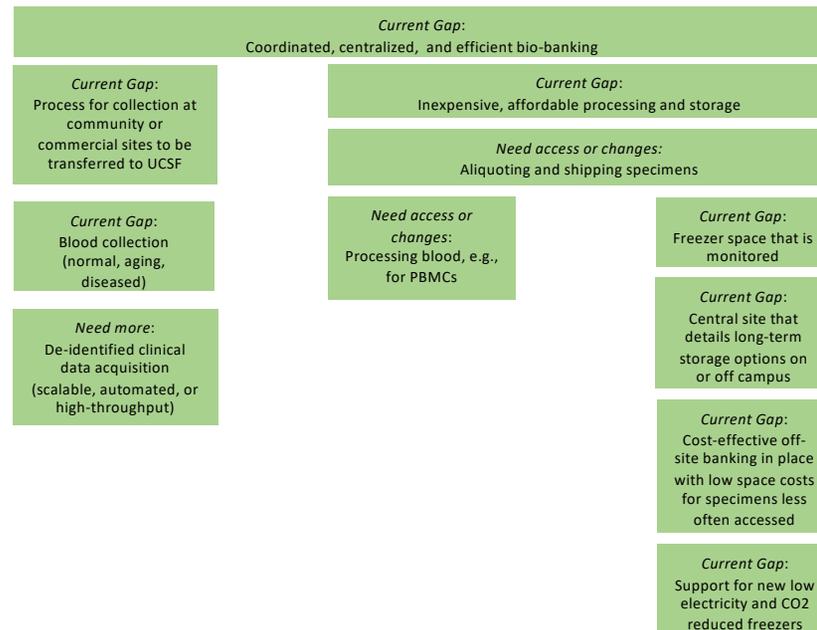
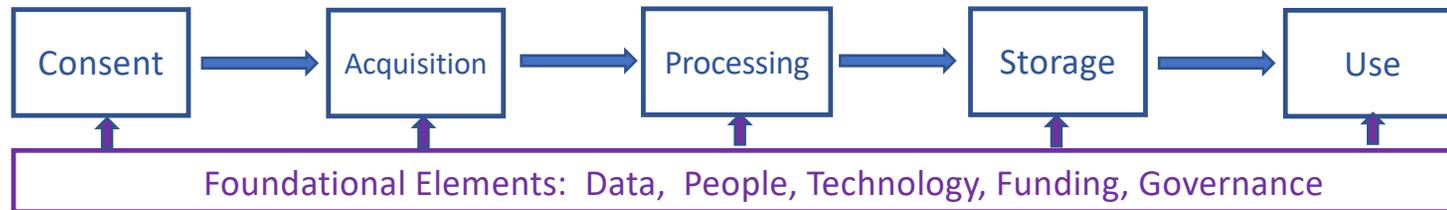
- Often not a logical source to pay the cost
 - Have to pay for it before you reap the value; the value is long-term

Other

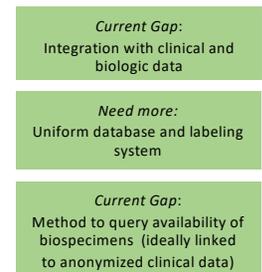
- Would other medical partners be interested?
- Two types of resources:
 1. Short-term (samples)
 2. Long-term (database) – invest in creating a resource that anyone could potentially access

Before retreat

Human Biospecimen Lifecycle Target State



Data Mgmt Solutions

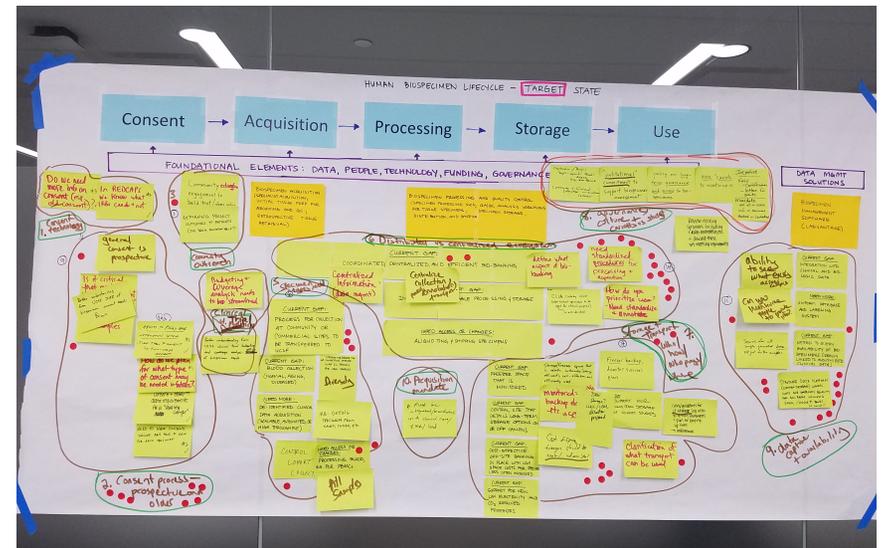


Target State – Gaps

Gaps in the target state were identified by participants and grouped into 9 areas listed below. Participants voted on the area that they thought **most important for BIOS to address**

They did not vote on area 1 which we already determined was a priority area.

1. Governance, culture, “carrots & sticks”
2. Distributed vs centralized ecosystem (14 votes)
3. Data capture & availability (11 votes)
4. Consent process (prospective and older) + consent technology (9 votes)
5. Storage & transport (who / how / who pays / where) (7 votes)
6. Specimen types needed (6 votes)
7. Community outreach (1 vote)
8. Clinical trial admin (0 votes)
9. Acquisition mandate (0 votes)



Target State

Top-priority gaps for BIOS

Small work groups

1. Governance & Culture
2. Distributed vs. Centralized Ecosystem
3. Data Management
4. Consent

Governance and Culture

Problem

- How can we affect culture change, and what role can a BIOS governance process play to support this change?

What strategies can we deploy to influence adoption of the BIOS program infrastructure?

1. **Free Services** - A strong incentive would be if services were free, supported by the institution
2. **Awards** – Provide funds for biospecimen projects that can only be used in the BIOS program
3. **Education** –Some people prefer to do things themselves, education needed to showcase the value of BIOS
 - Make hidden costs visible, i.e. cost of lost specimens due to poor record keeping, cost of electricity to run - 80oC freezers (\$2M per year?)
 - What does BIOS provide and what are the benefits of using BIOS vs doing it yourself
 - Allow a more streamlined IRB process if you use BIOS for patient consent, etc
 - Future Proofing - New NIH regulations on biorepository standards will be implemented and BIOS already meets those standards so you don't have to worry about compliance
 - Specimen are in secure storage facility
 - Integration with data resources – show how using BIOS makes data management easier
 - Increase value of specimens for possible future monetarization of biospecimen collections
 - User retains control of specimens but expectation that sharing will happen, so that community resources are optimally used (e.g Premier model provides free storage but samples can be used by others), develop model of how to prioritize access to limited samples.
 - How can we spread the word and educate community
 - Include information about BIOS in human subject training
 - Talk to two people about BIOS every week
 - Can we include education about BIOS in graduate level programs?
 - Workshop on Human Research for Junior Investigators?
4. **Customer service** - BIOS needs standardized but flexible services to accommodate a wide variety of needs and a can do attitude to promote reputation.

Group members:

Brian Smith
Elizabeth Sinclair
India Hook-Bernard
Aleks Rajkovic

Role of User Committee (Advisory)

- If user voice is part of decision making this will increase relevance and trust and help with buy-in and socialization of BIOS program.

Role of this group – BIOS Advisory Committee

- Issues are complex and prioritization of needs is necessary, which this committee can help with.
- Can provide support to influence related groups such as the IRB
- Can socialize the program to biospecimen owners and potential funders
- Can provide faculty support to requests for funding and support prioritization of BIOS program
- Can help to recommend funding models and sources – for example implementation of “tax” to be included in funding requests that involve the use of human biospecimens and philanthropic funds. Can make recommendations for what costs should be.

Distributed vs centralized ecosystem

Group members:
Scott Vandenberg
Suneil Koliwad
Janice Schwartz
Hal Collard
Josh Adler

Problem

- Current acquisition and processing does not reliably meet the needs of investigators, ensure quality assurance & patient safety standards, or meet institutional goals for maximal use of specimens and access for investigators.

Key elements of strategy

- SOPs
- Technical expertise
- Qualified team
- Audit mechanism
- Dissemination / education

Primary Stakeholders

- Investigators
- Institution
- BIOS

Resource implications

- \$ - long term
- People & expertise
- Integration – IT infrastructure

Critical success factors

- Prioritization by leadership
- Flexible depth of engagement

Conclusion – Standardization may be a more achievable goal than centralization

Data management

Group members:
Dave Morgan
Helene Bour-Jordan
Amy Lockwood
Sharat Israni

Problem

- No way to access data about all biospecimens

Key elements of strategy

- Transferring as many specimens as possible to LabVantage (data repository)
- Defining the standard data structure (what elements) for each specimen
 - A dictionary that can be used in many systems (valid data ranges, etc.)
 - The most useful to the community
 - Meets regulations (HIPAA, etc.)
- Design tools based on the kinds of questions people ask (e.g., virtual biobank, LabVantage, others) & link compliance & training to use
- Who can access these data / tools?

Primary Stakeholders

- All PIs interested in research w/ human samples
- “Lab staff” – the people collecting, processing, storing – everyone who touches a specimen
- Atul Butte – the group linking research w/ clinical
- Clinicians – who can investigate research data
- Patients
- Humanity

Resource implications

- Political will
- \$\$\$ for implementation & maintenance
 - Personnel
 - Licenses
 - Support

Critical success factors

- Governance / authority to incent people to use “the commons” data repository / LabVantage **or** standard data structure
- \$ - institutional priority / support, get \$ from
- Carrots & sticks (requirements)
- Make the use (data entry, queries, etc.) as simple, and resource limited. Frictionless.
- Buy in from users

Consent

Group members:

Ben Braun
Meyeon Park
Paul Volberding
Vincent Chen

Problem

- Uses of samples are constrained by the consents

Key elements of strategy

1. Consent standardized process (“rule book”) (pre-consent)
2. Data infrastructure for consents
 - What was consented / original consent form
 - Sample quality
 - Metadata / annotation of clinical conditions, handling, etc.
3. Policy regarded out-of-date consents

Primary Stakeholders

1. Biobank depositors
2. Users
3. IRB
4. Patients

Resource implications

- Centralization of costs (not everyone can afford infrastructure)
- Building online consent (efficient population of data infrastructure and “searching”)
- Prioritization of data entry of consents (based on usage)

Critical success factors

- Buy in / awareness from all stakeholders (1-4); university

It was a long meeting but everyone stayed focused!



Debrief

What went well

- Learned a lot
- Everyone engaged
- Power of the collective mind (esp. prioritization)
 - Very productive
- Facilitation well organized – kept people engaged
- Fun and productive

What we could improve

- Patient voice missing
- Need convincing argument about why use BIOS
- Need communication strategy
- Still question of larger context of BIOS role

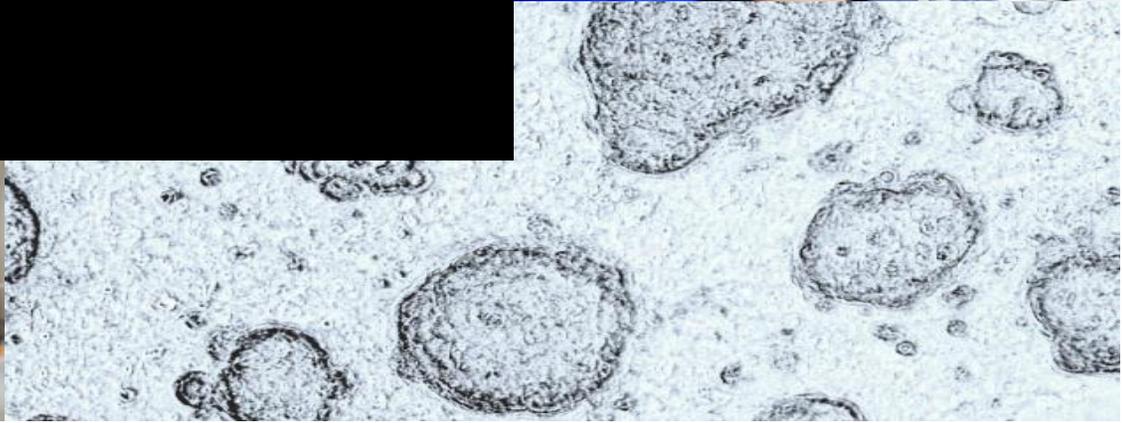
Debrief

Some important next steps

- Need communications strategy
 - Convincing argument about “why BIOS”
 - Give people assignments to talk to others (so they can include info / link in all their newsletters, not just on the website)
 - Tell success stories
- Action Plan for leadership engagement (SOM chairs)
- Strategy of communicating this to Mark Laret
 - Patients link w/ biospecimens
- Consider competitive landscape
- Provide updates outside of meetings



UCSF



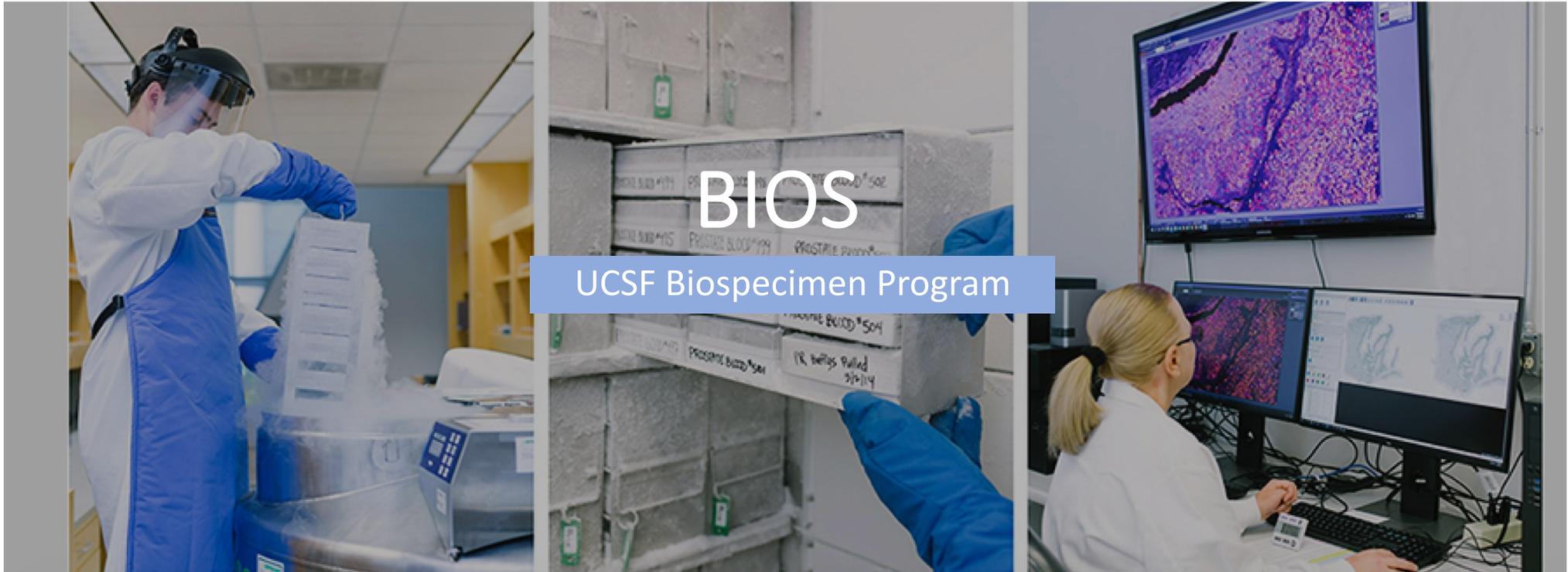
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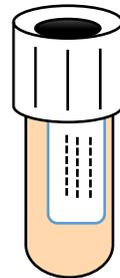
Access to high quality Biospecimens is fundamental for Biomedical Research and essential for development of Precision Medicine

The UCSF Biospecimen Resources (BIOS) Program was created in 2015 to support excellence in biobanking and increase the value of biospecimen collections

BIOS projects address the identified gaps by providing:

1. Centralized/coordinated standardized infrastructure
2. An enterprise software platform for biospecimen data management

<https://bios.ucsf.edu/>



High Value Biospecimens are:

Consented
Quality Assured
Highly Annotated
Clinically Linked
Searchable

Insufficient Biospecimen Infrastructure

We have many independent large and small operations engaging in all stages of the biospecimen lifecycle

- Lack of standardization, quality control and compliance
 - Variable specimen quality
 - Compromised patient protections
 - Reduced eligibility of UCSF to participate in funding opportunities and industry collaborations
- Inadequate and non-compliant data management
 - We don't know what we have and we recollect the same specimens
 - Maintain freezers full of specimens that are never used creating a shortage of freezer space
- Lack of coordination and duplication of services
 - Inefficient use of resources
 - Insufficient resources to provide high quality services
- Pricing, capacity and hours of operation are high variable
 - Uneven access for researchers to biospecimen services

Greatly limits the potential for research and support for precision medicine



BIOS

Progress and Success



Biospecimen Acquisition



**Biospecimen Processing
& Quality Control**



**Biospecimen
Management Software**

Goal: Standardization Across Biospecimen Lifecycle



Reorganization and consolidation of existing HDFCCC cores into a single Campus Core, the **Biorepository and Tissue Biomarker Technology Core (BTBMT)**.

- **Reduce Redundancy and Increase Efficiency**
- **Improve Quality** - SOPs for collection of individual tissue types and improved standardization and richness of specimen processing annotation
- **Increase Compliance** - meets NIH best practices for biospecimen management and regulatory compliance standard for electronic health care information (21 CFR Part 11)

Fluid specimen processing cores and banks

- Performed analysis of services, strengths and problems



BIOS

Progress and Success



Biospecimen Acquisition

Goal: Improved Consent Management



- Implemented a Universal/Broad Consent that allows consent of majority of diagnostic categories, including healthy adults, in the UCSF Health System for collection of multiple specimen types
- Consented patients can be recalled for specimen donations and centrally coordinated consent allows sample derivatives from one patient to be distributed to multiple investigators for different studies

Next Steps

- Universal/Broad Consent protocol is currently under IRB review for return of genetic results to patients
- eConsent video is under development for MyChart and tablet implementation will allow scaling of patient consent across UCSF Health System.

Goal: Centralized Biospecimen Collection Infrastructure

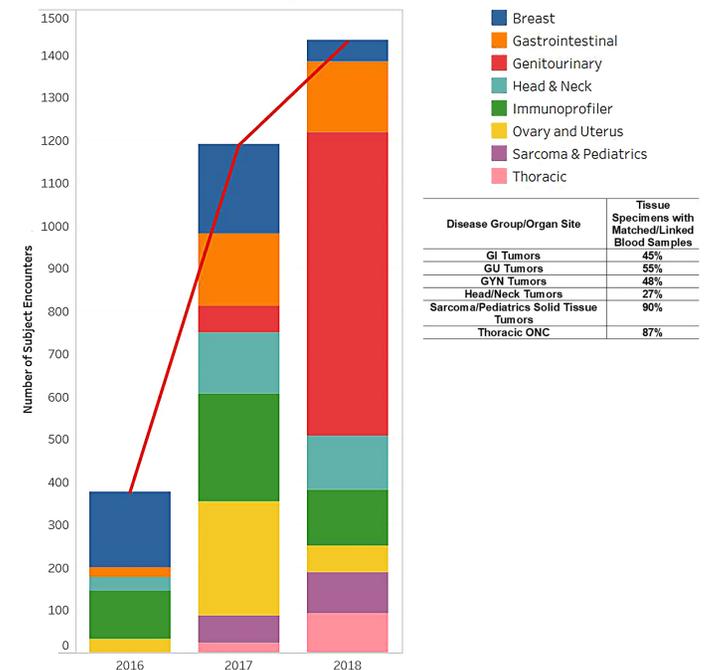


BIOS Tissue Acquisition Team has replaced the need for tissue collection by individual study groups at all campuses and serves 8 surgical groups, all 3 Interventional Radiology Clinics and Cancer Center Clinics

Centralized Acquisition Service (qualified pathology assistant)

- Ensures integrity of diagnostic specimens and improved specimen quality
- Reduced workflow disruptions in the OR, clinics and Pathology
- Improved efficiency

Tissue Acquisition 2016-2018





BIOS

Progress and Success

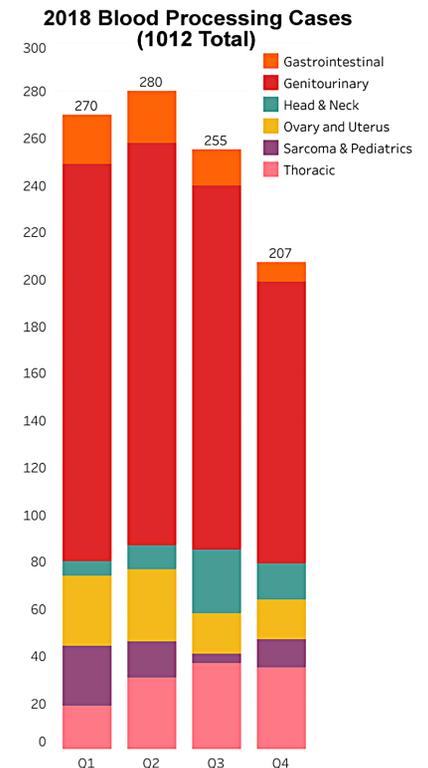


**Biospecimen Processing
& Quality Control**

Goal: Expanded Specimen Processing and Storage



- Matched or linked blood collection for tissue specimen, special and after-hours processing
- Production of viable cells for Xenografts and Organoids to support preclinical testing models
- Built a scalable process for blood that can be expanded to accommodate the processing of large volumes of specimens for omics studies
- Secure managed freezer storage capacity is being expanded by improved data management

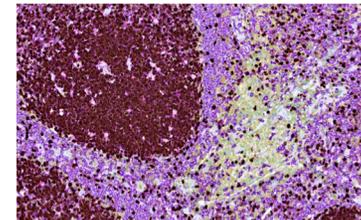
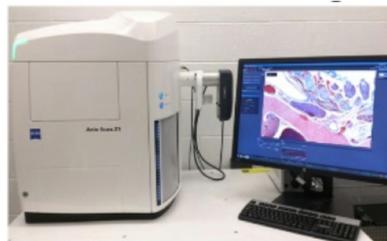


Goal: Provide Image Analysis Infrastructure for Tissue Biomarker QA/QC and Discovery



Deployed state-of-the-art technology for high-throughput biomarker detection and image analysis and developed new detection methods

- Implement QA/QC workflows to obtain high quality tissue specimens
- Provided searchable tissue digital images archive to improve access to tissue specimens
- Provide advanced analysis services and advanced training for self use customers
- Begun to build expertise and develop training for analytical tools





BIOS

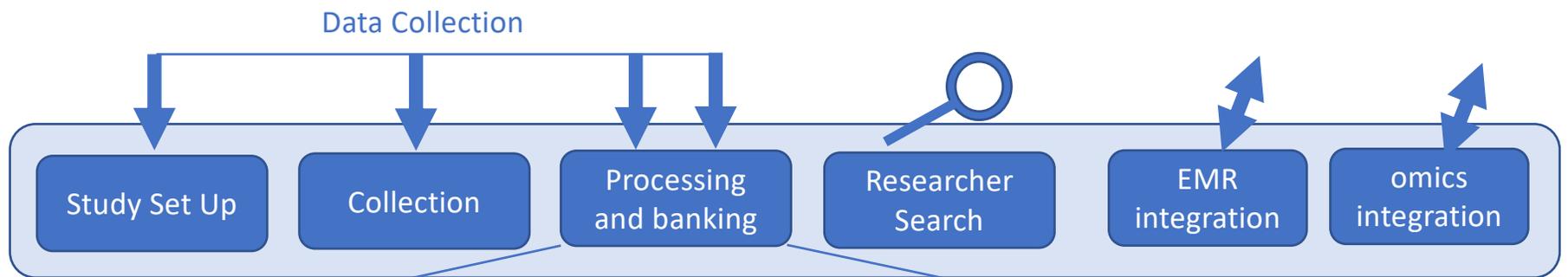
Progress and Success



**Biospecimen
Management Software**

Goal: Provide modern, enterprise solution for biospecimen lifecycle annotation and data management

LabVantage



Records detailed biobanking workflows including tracking specimen history for each aliquot: including sample collection method, sample containers, processing method final sample type, volume and container and retains parent and child relationships as samples are processed to different sample types (e.g blood>plasma>RNA)

LabVantage Implementation

- To develop common requirements and global features we selected Biobanks that represent the different UCSF workflows.
 - AIDS Specimen Bank
 - Cancer Immunotherapy Program
 - Memory and Aging Center Fluid Biobank
 - CTSI Clinical Research Services
- These banks have tested implementations configured for their business models and we are working to implement **major enhancements** to the system based on feedback from pilot banks
- HDC Cancer Center banks implementation will begin this year, goal to have approximately 35 banks implemented in total

LabVantage Challenges

- **Vendor Issues**
 - Business model inefficiencies - requirement gathering, building and configuring software for our needs
 - Software insufficiencies – some basic functionalities lacking and expensive to add
- **Specimen Bank Issues**
 - Enterprise software requires compromise, as configuration to specific business practices is limited.
 - Values of bank for more efficient software are not aligned with values of researchers and institution for improved documentation, annotation, visibility, compliance etc
- **Data Migration**
 - Expensive and time consuming for bank and our team, significantly delaying implementations for banks that have many years of data.

Biospecimen Storage Strategy



Complementary to BIOS

Brian Smith AVC Research Infrastructure and Operations

Steering committee: SCM, BIOS, ASB and Office of Sustainability.

Goals:

1. **Disaster Readiness**
2. **Energy efficiency**
3. **Increase space for biospecimen storage**

Options being explored for expanding storage

- Outsourcing to commercial company for long term storage?
- Lease space from Blood Centers (build out 10,000 sf)?

How should biospecimen storage be managed?

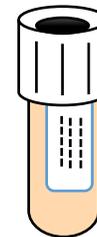
Freezer
Warehouse



Managed
Biorepository

BIOS Challenges

- Collection and storage of high quality biospecimens is expensive. Limited short-term funding makes long-term planning challenging
- We can build it but will they come? Researchers clearly want more central services but they don't want to/can't pay the costs and fear loss of control.
- No institutional mandate or guidance on compliance and best practices
- Competing values of banks vs researchers vs institution
- Long timeline to implement services
- Number of fluid cores and banks with overlapping services



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BIOS Team

Scott Vandenberg
Helene Bour-Jordan
Tasha Lee
Mingyue Zhou
David Aaronson
Sudeep Basnet
Nicola Gabancho
Emily Davis
Vincent Te
Vincent Cox
Bryan Hughes
Candice Pyun

Biospecimen Landscape

Survey

Apart from BIOS what infrastructure and/or programs are you aware of that support the human biospecimen lifecycle at UCSF

Which needs related to human biospecimens are currently not met by BIOS or other infrastructure