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### Breaking Barriers: Cultivating a Collaborative Infrastructure in a Hybrid Academic Community Cancer Center

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## Introduction

Human biospecimens (tissues and fluids) are an essential foundation for effective translational and genomics-based cancer research and have proven critical for the development of personalized cancer medicine. The demand for more high quality and clinically annotated biospecimens and the challenge of finding them to conduct clinical research or validation studies have grown rapidly, primarily due to an unprecedented level of genomic, post-genomic and personalized medicine research. The increased complexity of biospecimen requests in terms of linked exhaustive clinical variables, biospecimen types, and multidimensional longitudinal clinical follow-up data has created new challenges but also opportunities for adapting existing collection and annotation strategies to supply the biospecimen needs of the future.

In response to this critical need, the Miami Cancer Institute (MCI) designed and launched a centralized Biorepository Program, to facilitate the procurement of disease-based and normal biospecimens by providing resources and services to expedite discoveries and its translation to more effective diagnostics and therapeutics.

Cultivating an internal collaborative infrastructure is critical for the success of new initiatives that require multi-departmental and multidisciplinary services. It requires a logistically cohesive and dynamic design to continuously enroll participants, collect fit-for-purpose biospecimens, and annotate them with clinical information, and a strong operations and regulatory oversight. Six pivotal Departments were identified to the collaborative effort: Scheduling, Surgery, Infusion Services, Laboratory, Pathology and the Oncology Data Mart team.

## Building the Collaborative Infrastructure: The Six Pivotal Departments

<b>Surgery</b> <ul style="list-style-type: none"> <li>Increased participant enrollment</li> <li>Expedited tissue procurement</li> <li>Surgeon Involvement</li> </ul>	<b>Infusion</b> <ul style="list-style-type: none"> <li>Increased participant enrollment</li> <li>Accessible, specific biofluid</li> <li>Collection for longitudinal studies</li> </ul>	<b>Laboratory</b> <ul style="list-style-type: none"> <li>Continuous peripheral blood draw at time of routine blood collection</li> </ul>
<b>Clinic</b> <ul style="list-style-type: none"> <li>Increased participant enrollment</li> <li>Medical Assistant support</li> <li>Clinic Operations support</li> <li>Physician involvement</li> </ul>	<b>Pathology</b> <ul style="list-style-type: none"> <li>Expedited tissue grossing</li> <li>Dedicated area for tissue processing</li> <li>Tissue Quality Control</li> <li>Archived tissue accessibility</li> </ul>	<b>MCI Data Mart</b> <ul style="list-style-type: none"> <li>Real-time cohort identification</li> <li>Biospecimen associated clinical data</li> <li>Alert development for longitudinal studies</li> </ul>

Figure 1. Collaborative Operational Model for patient consent and collection of fit-for-purpose biospecimens.

## Integrative Processes

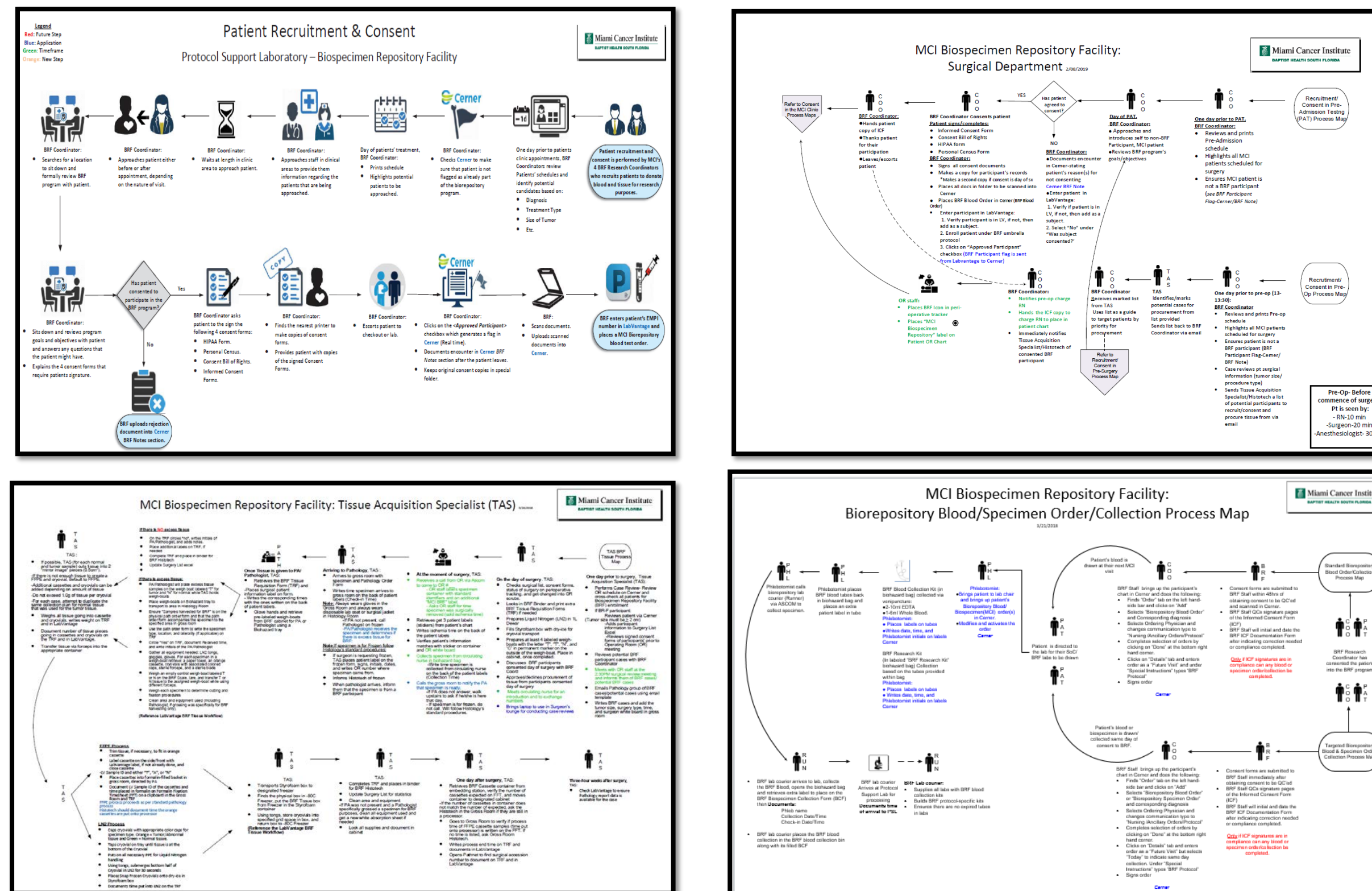


Figure 4. Operational workflows depict the integration of the Biorepository Program within Infusion, Clinics, Surgery, Pathology and Laboratory Departments. All pertinent staff are trained on the processes set forth using these workflows, that are considered the operational blueprints of the Program.

## Collaborative Strategy

### Staff Meeting Presentations

- The Biorepository Program common goals and updates are presented at the various departmental staff meetings to disseminate current research involvement, share quality measures and growth data, identify challenges and seek ways to improve processes.

### Departmental Rounding

- As ambassadors of the Biorepository Program, the BRF staff rounds on all pivotal departments on a weekly basis. Our presence within these Departments remains consistent so that the expectation is set; the Biorepository Program delivers excellence to the research community and contributes to BHSF standards.

### Leadership Meetings

- Monthly/Quarterly meetings with the Departments' leadership teams provide a forum to discuss progress, implement changes, and facilitate program expansion.

### Bi-weekly MCI Data Mart Meetings

- Continued work on complex data accessibility and building data analysis capacity.
- Implementation of strategies to build alerts within the EMR for multi-pronged, longitudinal research requests.

### The Biospecimen and Data Release Committee (BDRC)

- Monthly meetings to review all requests for use of biospecimens and/or data for research purposes or to initiate a prospective biospecimen collection.
- Members represent key institutional stakeholders and Departments.

### The BRF Dashboard

- Dynamic and real-time dashboard published to display the Biorepository Program productivity and availability of biospecimens for research

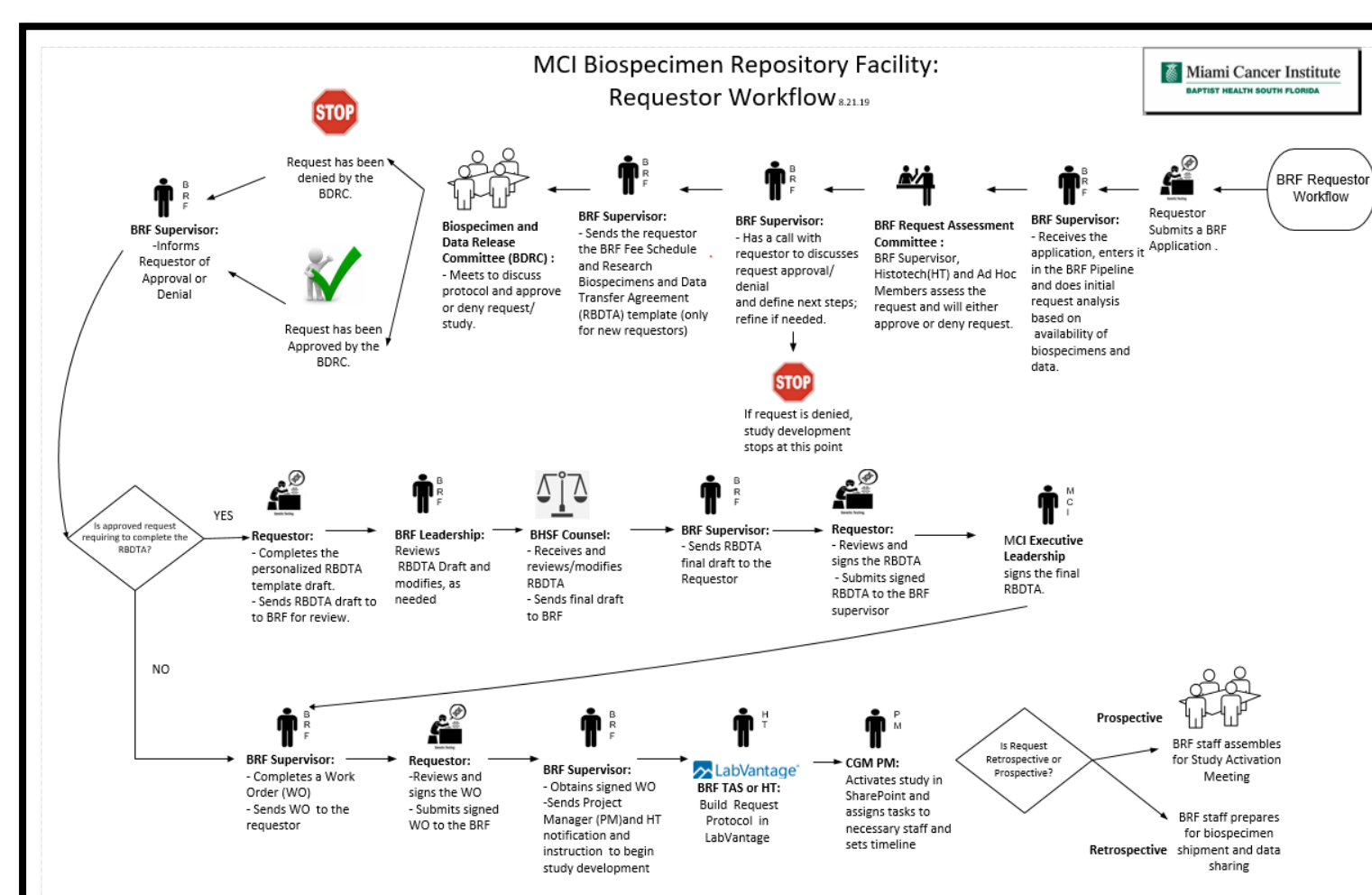


Figure 5. The Requestor Workflow details the process by which all requests to the BRF are handled. Biospecimen and Data Release Committee approval is the gateway for all research endeavors.

## The Development of the BRF Dashboard: An Illustrative Performance Tool

Key Performance Indicators	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	To Date
Total number of patients consented	33	61	115	142	145	133	104	155	245	243	242	169	1787
Total number of patients with blood collected	21	21	44	97	97	83	55	74	138	138	126	123	1017
Number of tissue biospecimen flash frozen	0	0	1	6	4	13	11	16	21	24	9	17	122
Number of tissue biospecimen preserved in formalin/QC	0	0	1	5	5	13	14	19	27	29	10	16	139

Figure 6. The 2018 BRF dashboard displays the gradual growth in enrollment and biospecimen collection that resulted from the pivotal Departments support.

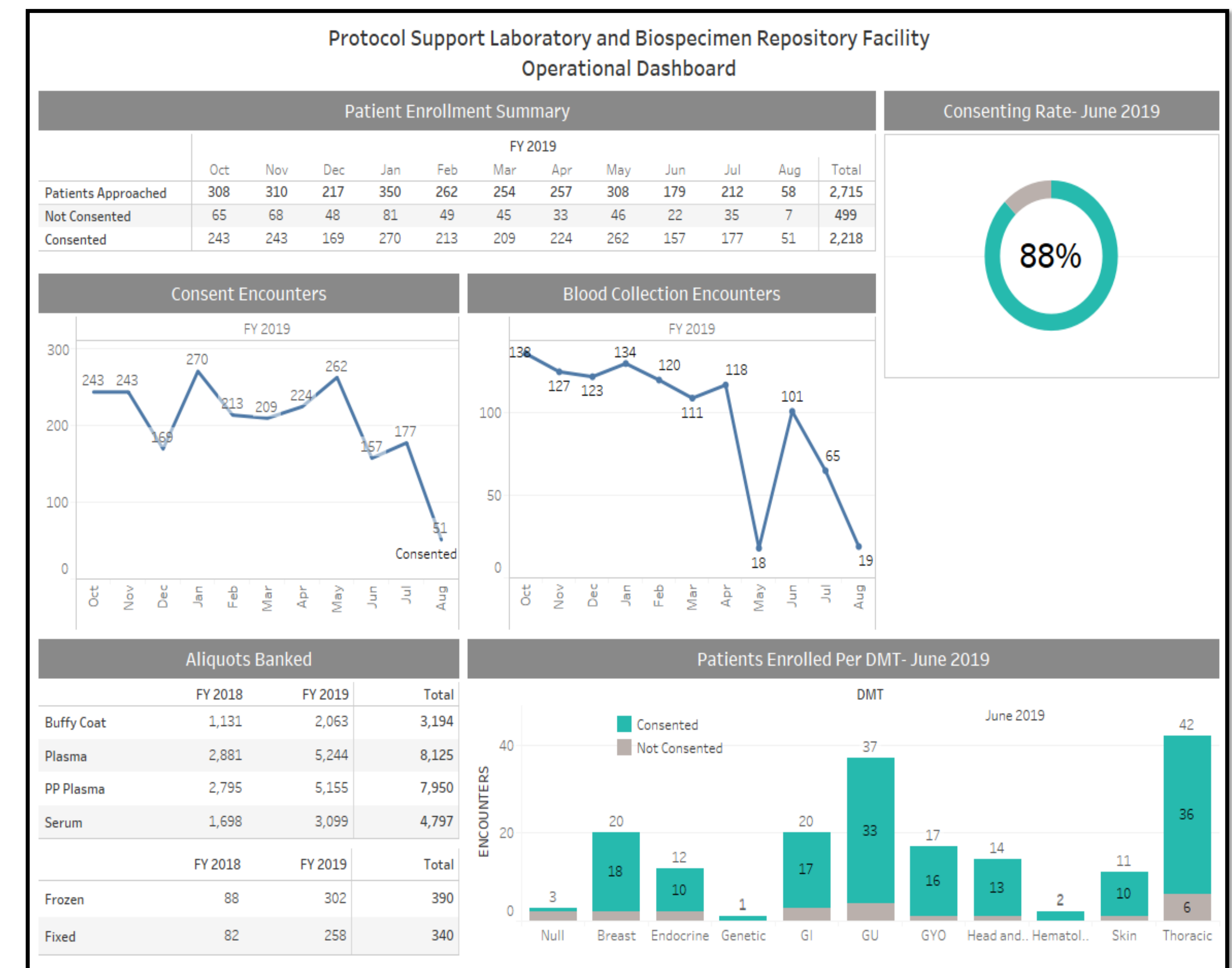


Figure 7. The 2019 BRF interactive dashboard provides real-time productivity data related to patient enrollment and biospecimen collection by disease site and illustrates how the various Departments' involvement directly impact productivity.

## Conclusions

- The Biorepository Program has been capitalized and integrates six pivotal Departments and uses a collaborative model to enroll patients and collect biospecimens for research purposes.
- An increase in productivity was observed in 2019, compared to the first year of operations. Patient enrollment increased by 52% and biospecimens banked increased by 46%.
- A culture shift within the collaborative Departments towards genuine support have resulted in a wealth of resources the Biorepository program can provide to expedite discoveries and its translation to more effective diagnostics and therapeutics.
- There is an exponential increase in requests of high quality and clinically annotated biospecimens from academic, industry and internal investigators.
- The Biorepository Program is well equipped to share these biospecimens in an expedited and compliant manner.

## A Shift in the Research Paradigm

- To fulfill the research requirements of the many intricate requests the BRF receives at a rather expedited pace, particularly from our affiliated university members, the collaborative infrastructure must expand to other Baptist Health South Florida locations. The processes shown here must be tailored to these locations and to the new patient cohorts targeted.
- The expansion of consenting capabilities to health care professionals as well as the implementation of an e-consenting platform will increase enrollment efficiency and collection of key biospecimens on real-time.
- The establishment of an IT platform for locating and sharing remnant biospecimens collecting for clinical purposes will increase the support provided by Baptist Health South Florida infrastructure to the generation of new knowledge and more effective diagnostics and therapeutics strategies.

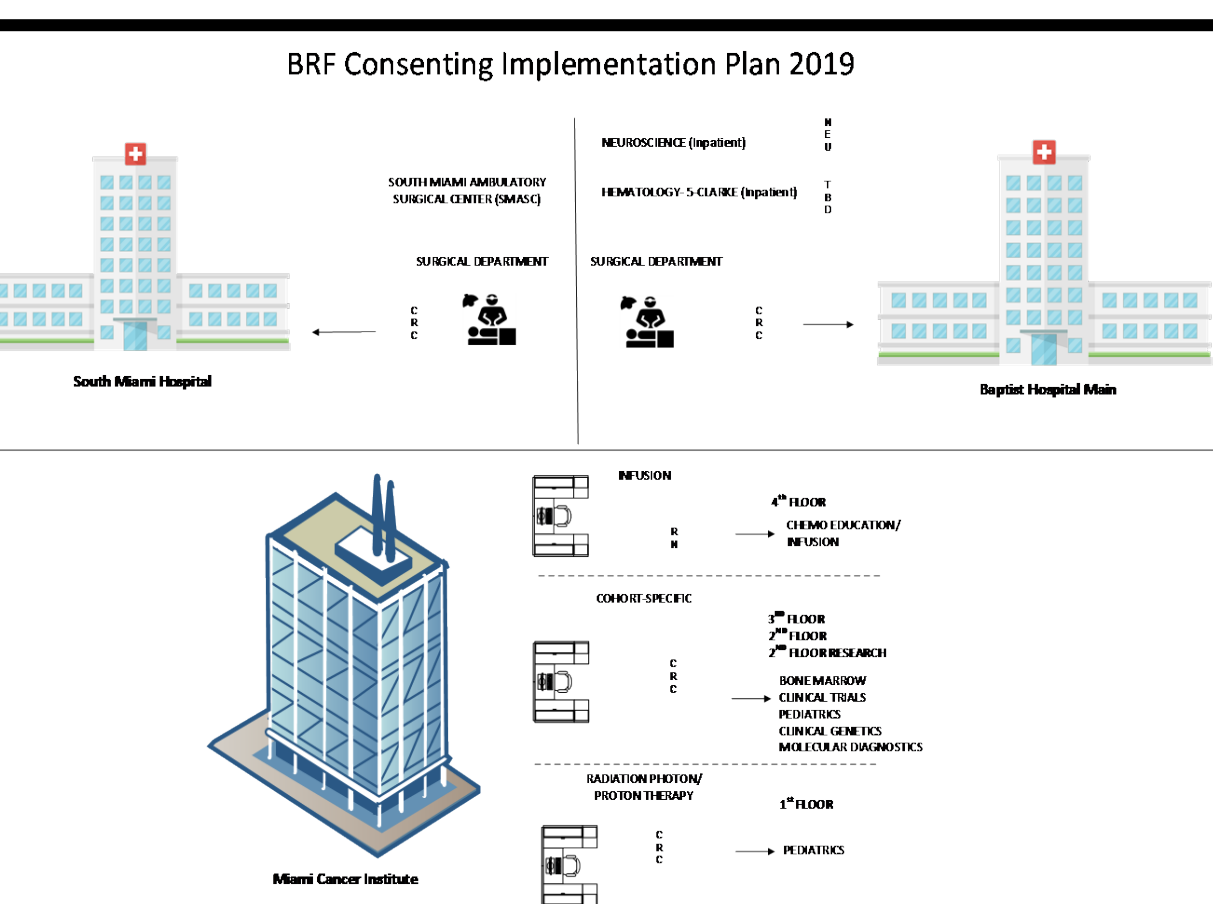


Figure 2. Collaborative Operational Model for patient consent began in January 2018 and has gradually expanded, allowing flexibility to target patients for enrollment.

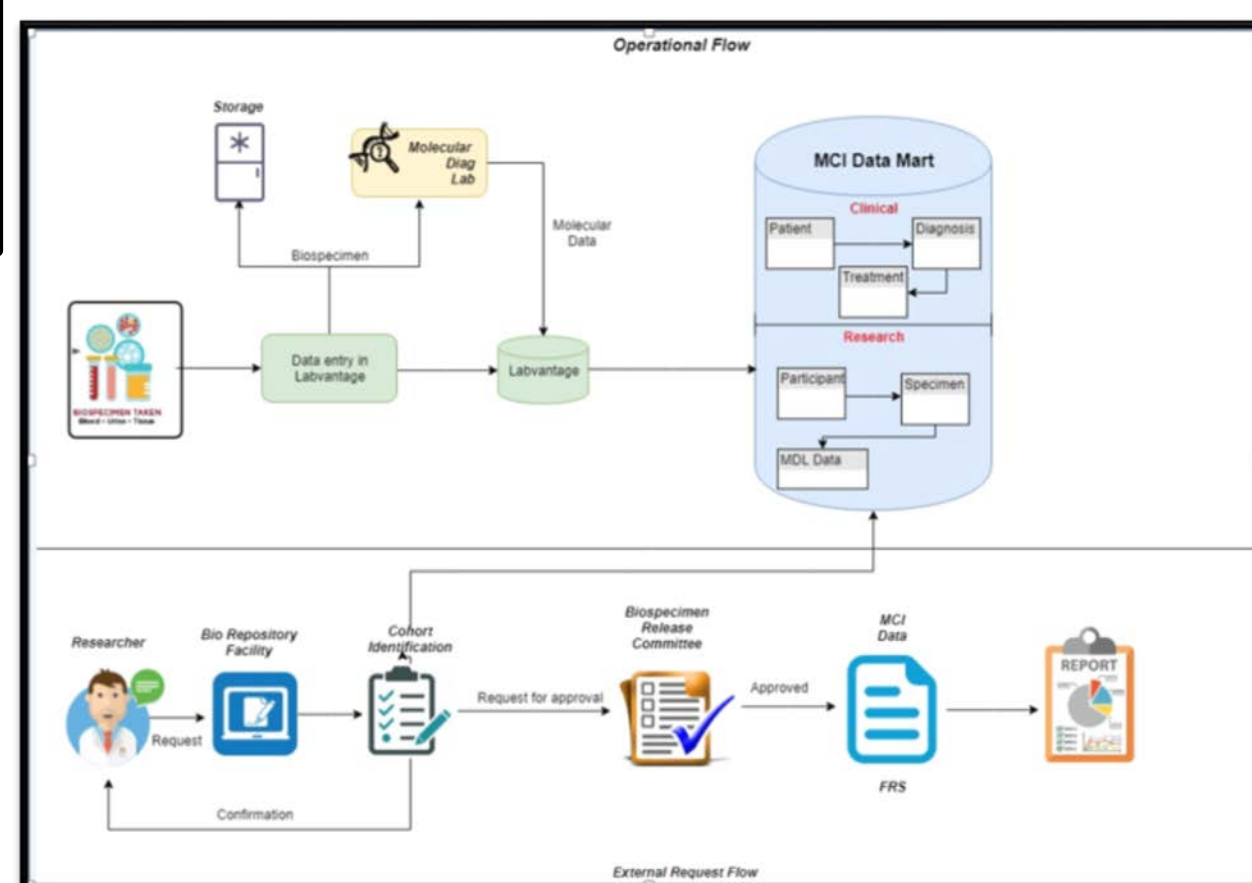


Figure 3. The MCI Data Mart provides associated clinical data obtained via EMR to allow for multi-disciplinary research in a variety of research initiatives.