

# McCain Genito-Urinary BioBank (MGB) at the University Health Network, Toronto, Ontario.

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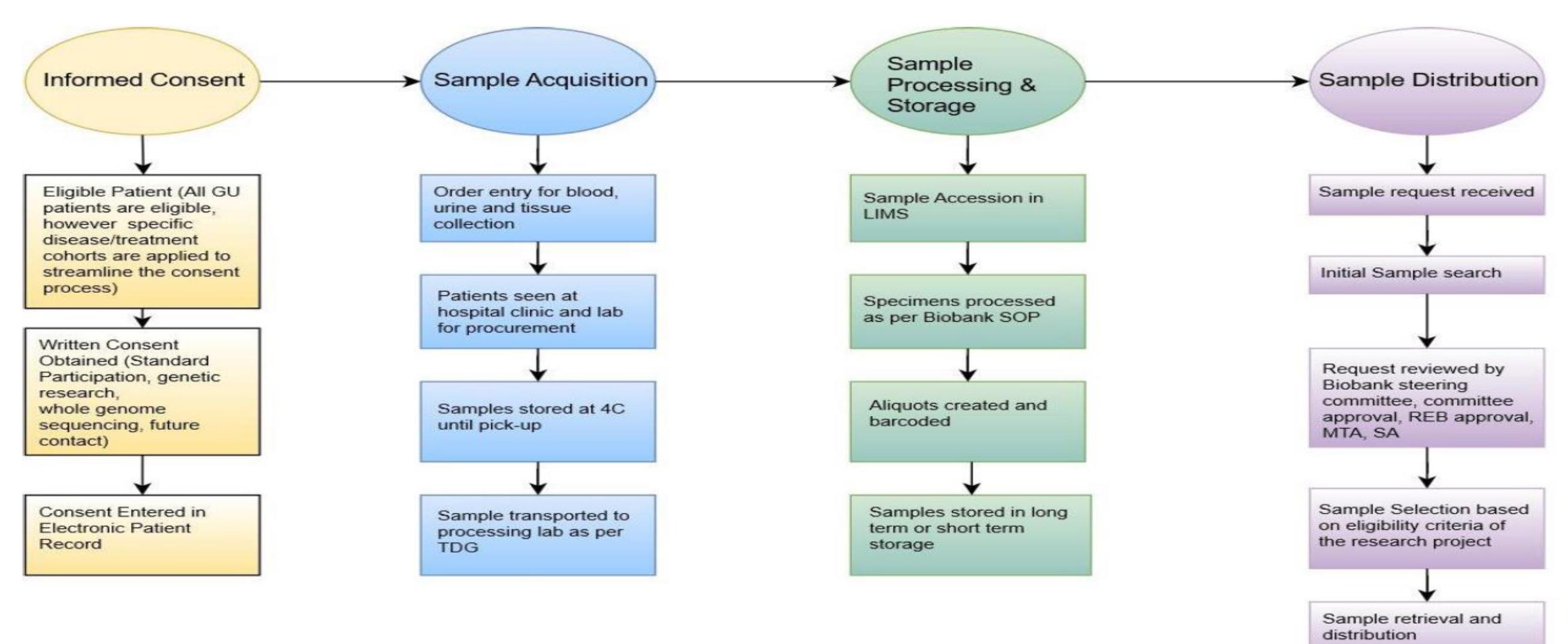
## Introduction

The McCain Genito-Urinary BioBank (MGB) was founded in 2008 as GU BioBank at University Health Network, a large tertiary health center in Toronto, Ontario affiliated with the University of Toronto. It was initiated to facilitate the discovery and validation of novel biomarkers in urology. The goal of MGB is to support biomarker discovery by collecting samples and metadata longitudinally across disease states and treatment lines. MGB is fully certified by Canadian Tissue Repository Network (CTRNet) and pursuing towards other Biobank accreditations offered at national and international levels and well acknowledged by industry standards.

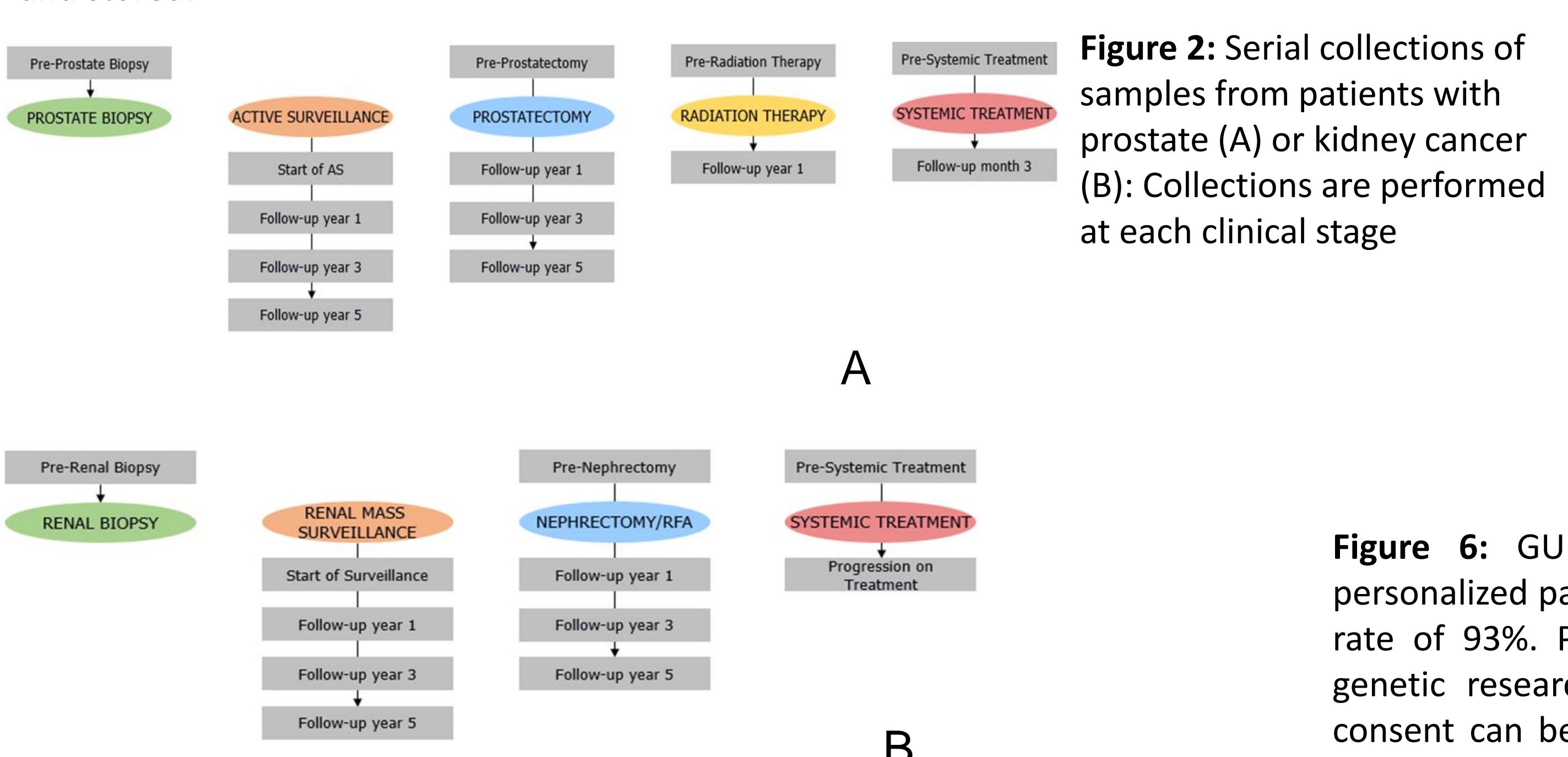
## Methodology

The McCain GU BioBank has mapped relevant clinical states for urologic cancer cohorts and established a systematic and clinically-integrated approach to bio-specimen procurement. All consenting patients provide specimens prior to, during, and following their treatment(s). This permits the collection of high-quality specimens and comprehensive standardized clinical data in a longitudinal fashion. Collection time-points are constantly updated based on input from physicians and researchers.

Liquid biospecimens (blood and urine) are collected at pre-determined time points, cataloged in the specimen database, processed, bar-coded, and stored in liquid nitrogen (LN<sub>2</sub>) vapor phase freezers for long-term banking. Currently, GU BioBank houses collected specimens in 15 LN<sub>2</sub> freezers and 5 mechanical freezers, with one new LN<sub>2</sub> freezer added every year to support the growing storage needs. The rapid progress in our understanding of factors affecting genito-urinary cancers has created demand for reliable biomarkers for diagnosis and treatment personalization.



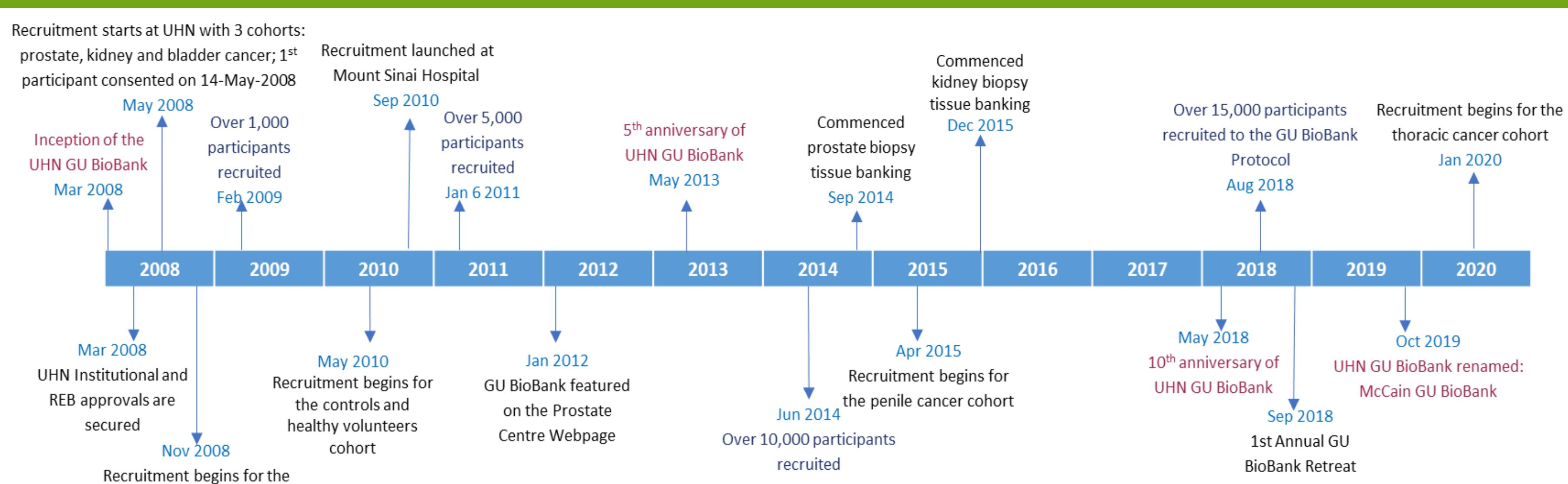
**Figure 1:** Work flow of sample collection and storage at MGB: Steps involved in operational workflow from obtaining informed consent to the distribution of specimens and their utilization in approved research projects. Through close integration with the out-patient clinics, informed consent and collection of samples can be conducted in dedicated space at the time of participants' clinical visits. Dedicated staff "embedded" in the clinics interact with the patients and physicians. Following collection, samples are transported to the MGB, where they are processed, registered, and stored.



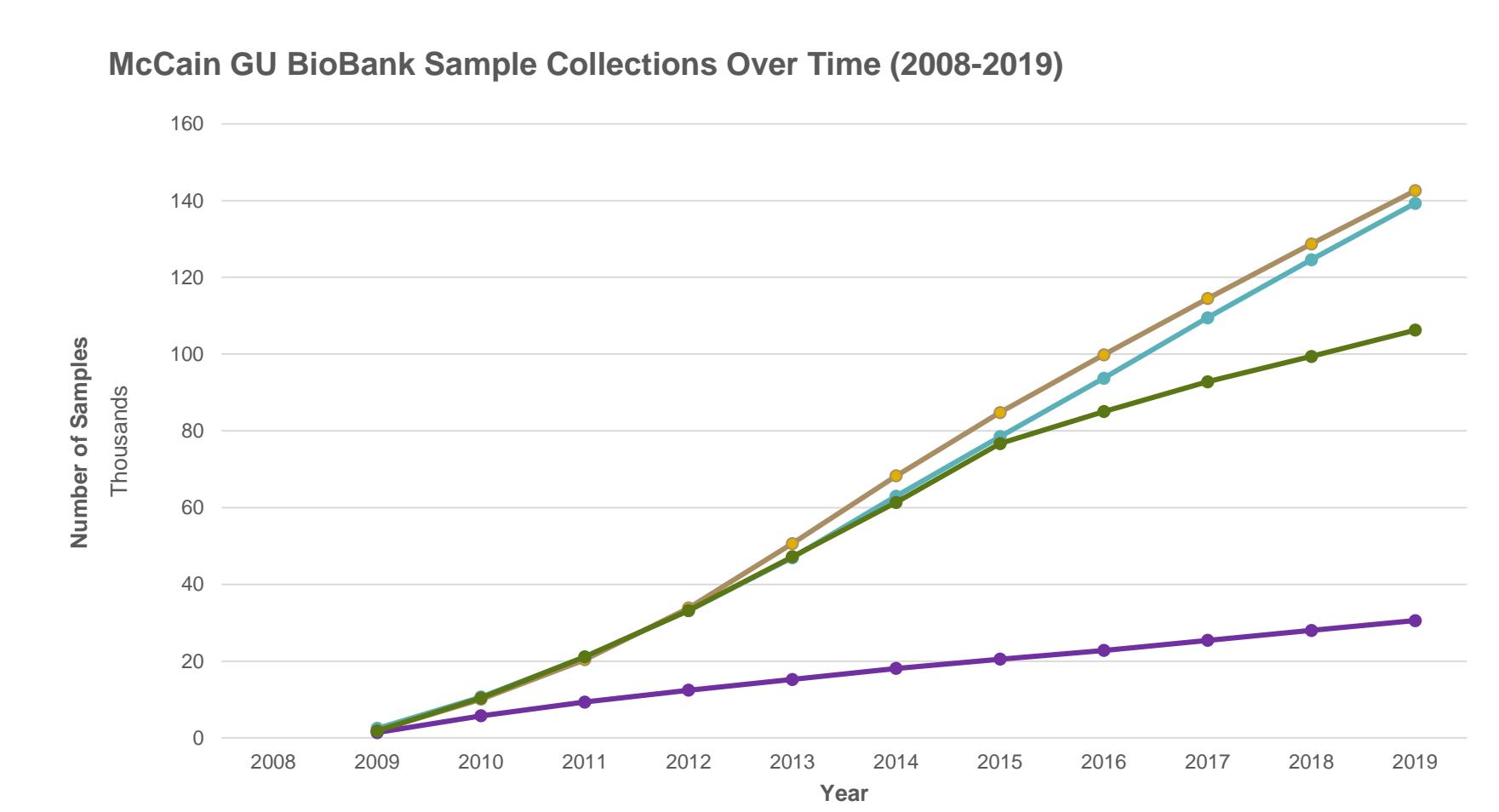
**Figure 2:** Serial collections of samples from patients with prostate (A) or kidney cancer (B): Collections are performed at each clinical stage

Specimen Supply	Protocol-specific biobanking	Biobanking Consulting:
High-quality biological specimens suitable for biomarker development	Blood/urine procurement	Protocol Development
Serial samples from patients	Clinical Trials	Grant writing support
Extensive clinical data available	Adverse event monitoring	Staff Training/Continuing Education
Data management	Biomarker development studies	Consulting on biobank procedures, budget development, SOP development, QA, etc.
DNA/RNA extraction	Sample transportation and processing	Consulting on Business plan development, regulatory applications, study design, etc.

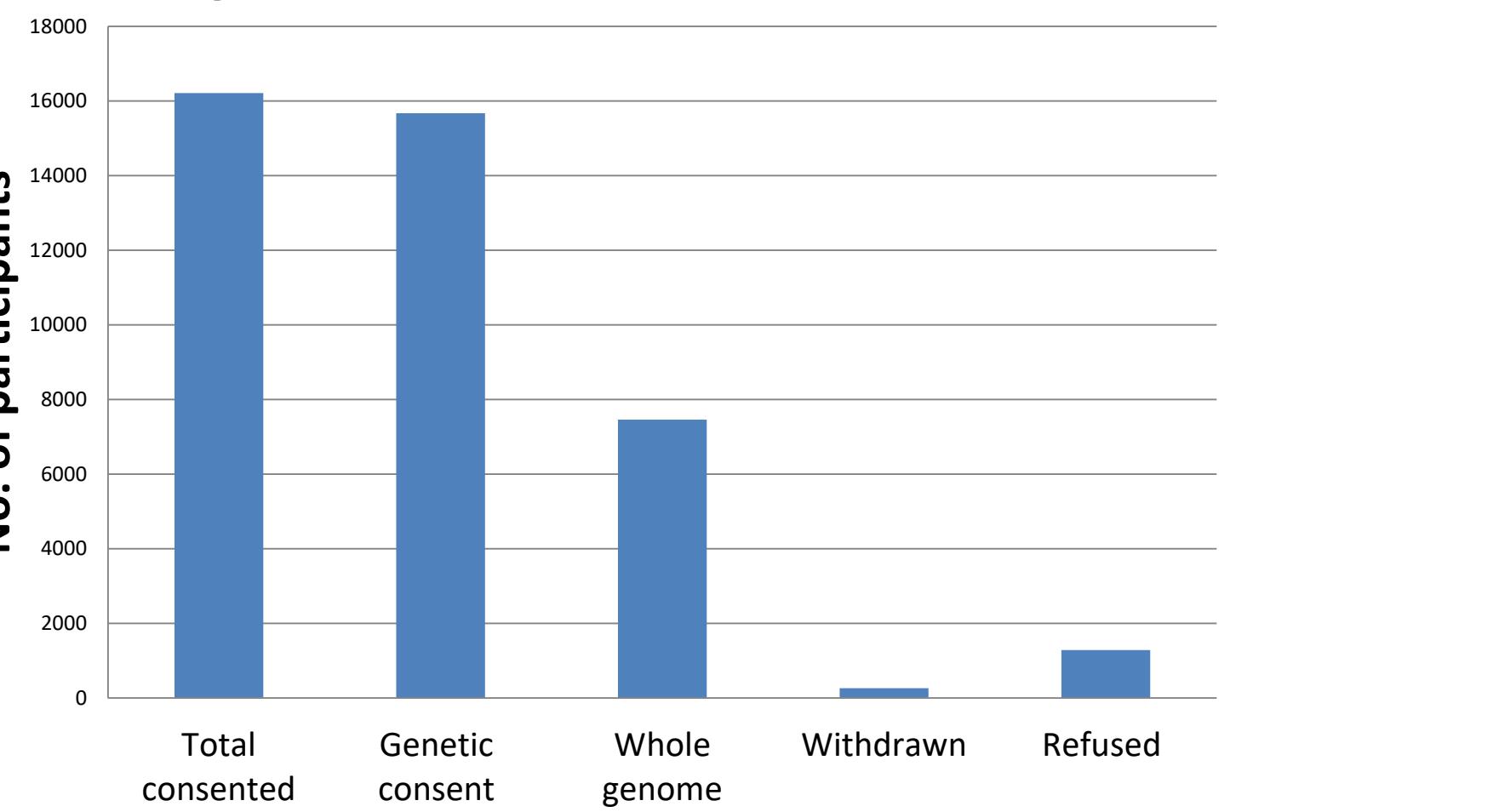
## Results



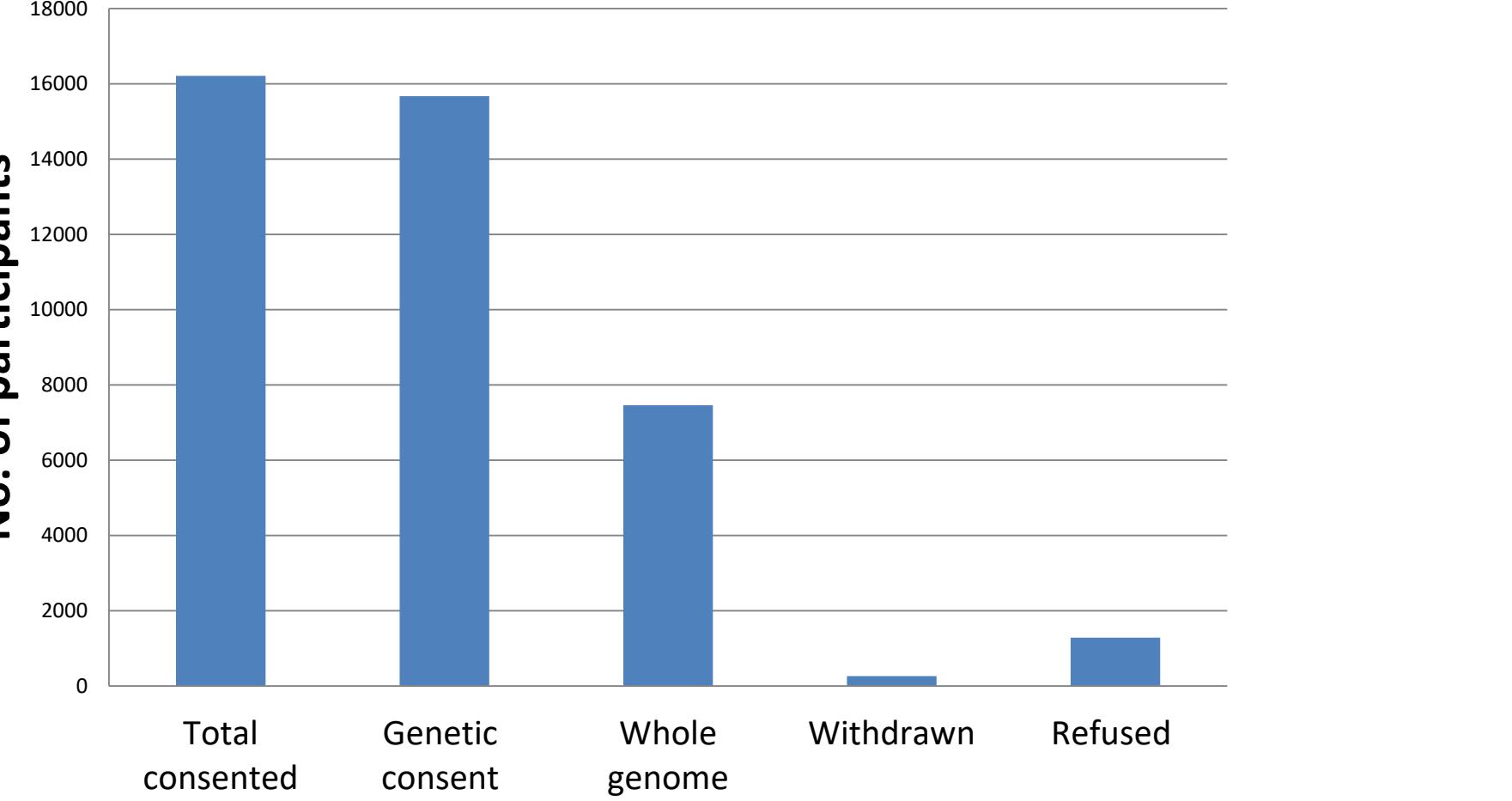
**Figure 3:** McCain GU BioBank timeline: Since its inception, over 16,000 participants have been consented to the program. The clinical follow up data of up to 11 years is available for the collected samples. Based on our most recent numbers, we have >5 years of clinical data associated with bio-specimens collected from more than 10,000 participants.



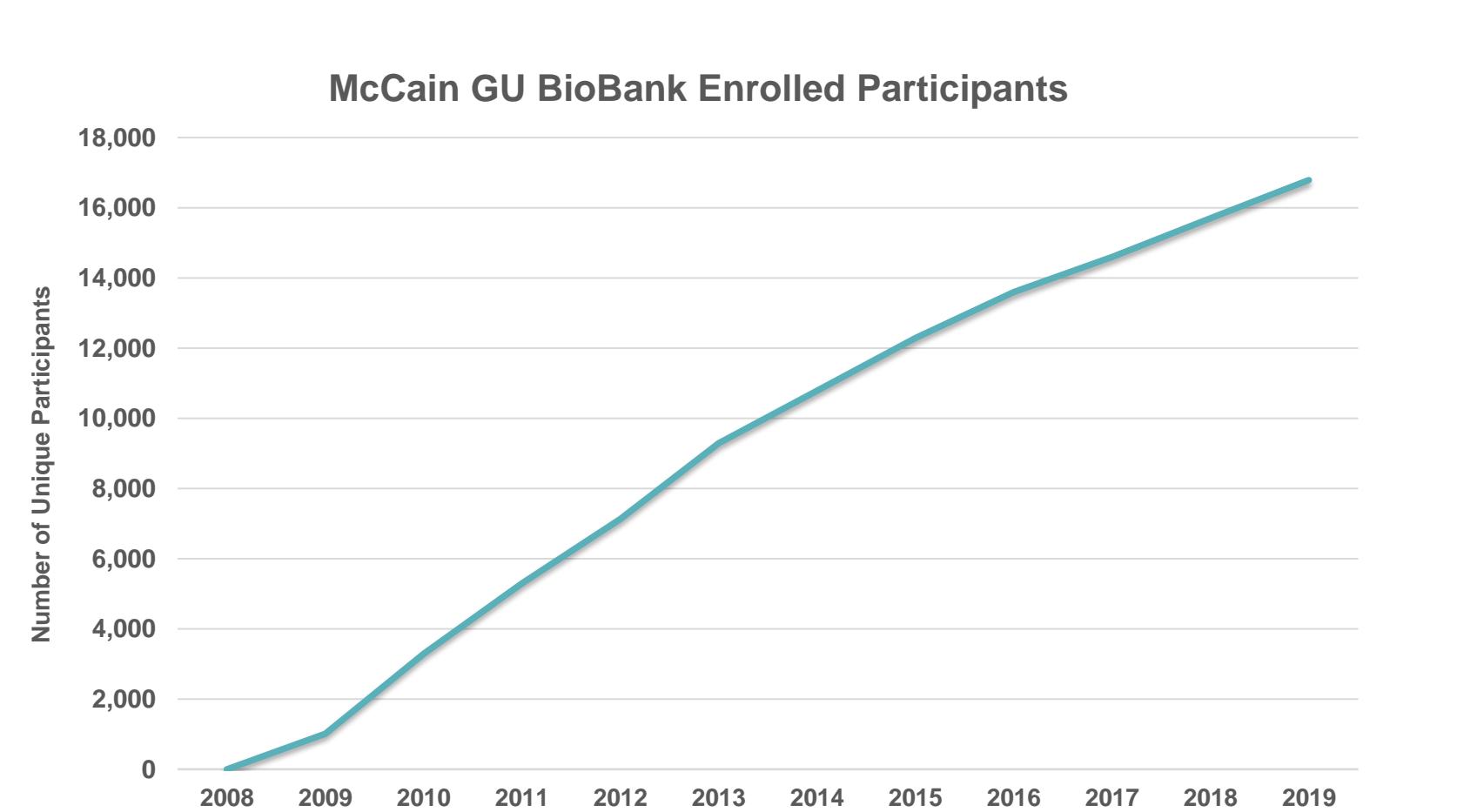
**Figure 4:** Number of stored specimens by sample type. Over the years, the types of collected specimens are adjusted in response to the scientific discoveries and the changing demand for specific bio-specimens. Specimens are collected from newly consented patients and as well serial collection from existing patients during their course of treatment.



**Figure 5:** Specimens collected by disease cohort: While prostate cancer makes up the majority of the biorepository's samples (reflecting the research interests of the initiating clinicians), renal, bladder, penile, and testicular cancers are also represented. Control samples from healthy volunteers are also available



**Figure 6:** GUB consent metrics: Through our extensive staff training program, personalized patient approach, & supportive institutional policies, we maintain a consent rate of 93%. Patients are consented for standard participation to Biobank program, genetic research, & whole genome sequencing. Specimens collected under genetic consent can be utilized for genomic studies whereas separate consent is obtained to allow whole genome sequencing.



**Figure 7:** Patient enrollment: Since its inception, over 600,000 biospecimens have been collected from 16,000 patients diagnosed with genito-urinary cancers.



**Figure 8:** Global collaborations with academic and industrial partners. Stored specimens have been utilized in more than 70 research projects, including proteomic, genomic, and epidemiologic studies, conducted through regional, national, and international collaborations. Research conducted generally focused on the development and optimization of novel biomarkers, with the aim of improving diagnosis, personalizing therapy, and facilitating the development of novel treatments.

## Discussion

The MGB continues to expand, with over 100 new participants consented each month. Being a Canadian Biobank, we are able to leverage the unique properties of the provincial health care system to follow the patients during their course of disease treatment and collect specimens in a non-biased, protocol-driven manner with strictly standardized processing, rigorously controlled pre-storage parameters, and extensive clinical data.

Due to the use of standardized collection protocols for each disease, McCain GU BioBank specimens can be utilized in retrospective-prospective studies to yield reproducible data that can be used in regulatory applications and high-impact publications. By accelerating biomarker development and deployment, MGB is developing approaches that will ultimately guide the personalization of patient treatment.

Continuing review of collection paradigms on the basis of a) changing clinical approaches, b) improved understanding of drivers of disease progression, c) demand from clients and d) develop new collaborations with academic and commercial entities within Canada and globally will be important next steps for MGB.

## Conclusion

Availability of high quality bio-specimens and associated clinical data translates to high quality research outcomes, which in turn aid biomarker discoveries in oncology research. Ongoing refinements of cost-recovery models, development of research collaborations at national and international levels, and upgrading of informatics systems are critical for sustaining the growth of MGB and enhancing utilization of stored samples.

## Acknowledgement

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