

## McCain GU BioBank (MGB)/Princess Margaret Cancer Centre; Toronto, Ontario

### INTRODUCTION & BACKGROUND

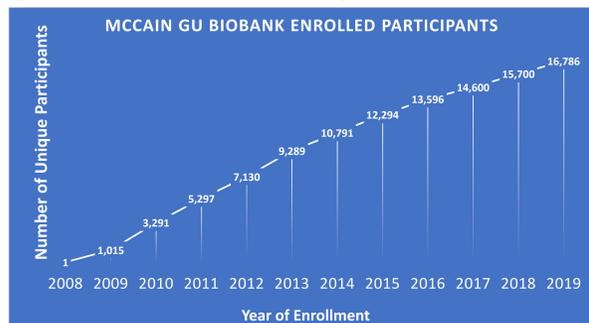
The McCain GU Biobank (MGB) is a biorepository based on specimen collections from consenting participants attending outpatient clinics within the genito-urinary (GU) oncology division at University Health Network in Toronto, Ontario.

Since its inception in early 2008, the MGB has been a great success, serving as a platform for cutting edge biomedical research including clinical trials and larger biomarker development trials both in Canada and internationally.

As the largest biorepository of genito-urinary cancer samples in Ontario, it corners the market for uro-oncological biospecimens with a unique multi-ethnic demographic population.

**The McCain GU BioBank has an industry leading consent rate of 93% and since its establishment has consented over 16,000 patients to the program.**

Figure 1 - McCain GU BioBank Participant Accrual



### OBJECTIVES

An analysis into McCain GU BioBank metrics was done to:

1. Assess motives behind consent and refusal to participate
2. Evaluate rationale for participant withdrawal
3. Optimize resource allocation within the biorepository
4. Develop a short and long term growth plan
5. Enhance participant accrual

### METHODS

A thorough evaluation of the biobank's consent rate over the last 10 years was conducted.

The analysis focused mainly on the 7% of individuals who have refused to participate with the biorepository.

- The consent and refusal rate is tracked using an electronic form, linked to the biobank's participant database.
- Diverse aspects were examined including reasons for refusal, hospital site or clinic where participant was approached and number of collections/specimens based on the protocol.
- Data was extracted from such database and compared with multiple parameters to determine the percentage of subjects who have refused, consented or remain undecided.
- A cross check was done with important events such as the incorporation of new clinics or collection sites, assimilation of new collection based protocols (e.g., Whole Genome Sequencing), modifications to the consent form, among other factors, to determine the impact these changes have had in the consent and refusal rate.

### THE GU BIOBANK AT A GLANCE

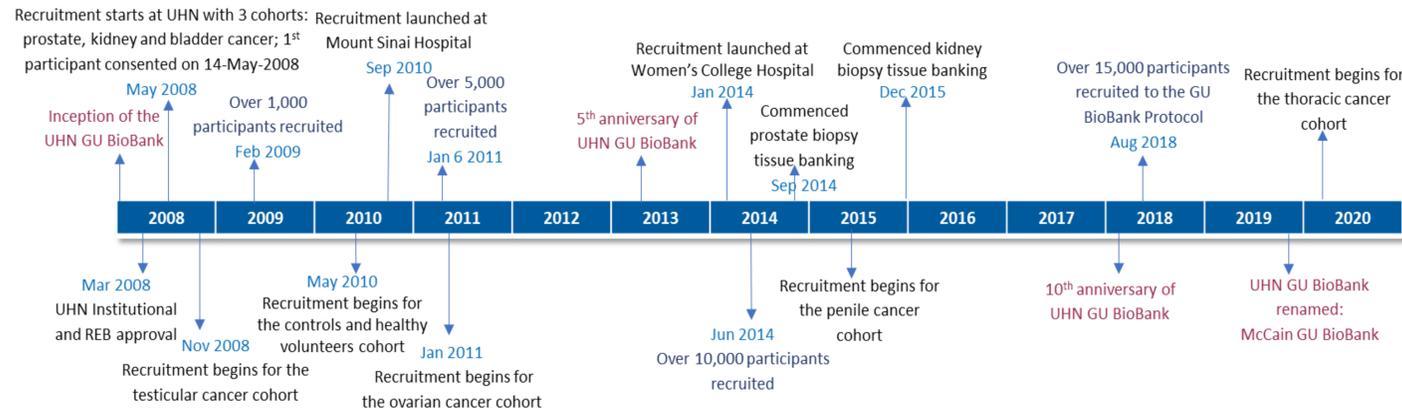
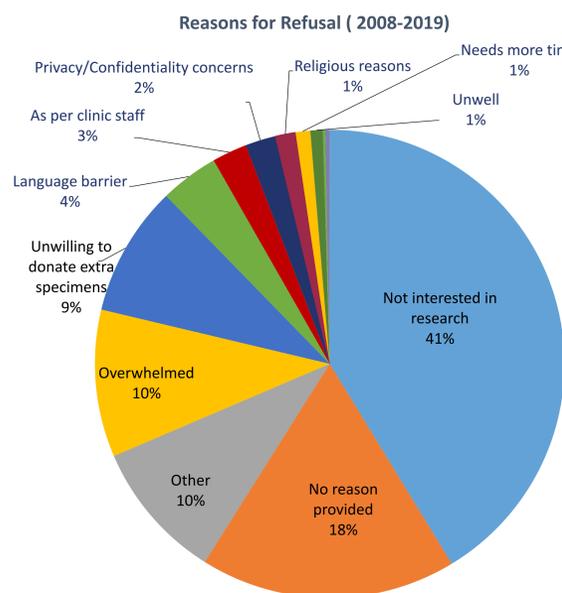


Figure 2 – McCain GU BioBank Timeline: Established in 2008 with the aim of facilitating the discovery of new diagnostic and prognostic biomarkers to achieve the ultimate goal of personalized medicine and improved outcomes for GU oncology patients. Since its inception, over 600,000 biospecimens have been stored to date from over 16,000 participants. These biospecimens are to be utilized in both retrospective and prospective samples. The retrospective collaborations have utilized approximately 25,000 samples to date and the prospective biospecimens are from over 30 study-directed banking protocols. The McCain GU BioBank has collaborated with over 60 entities, both locally and globally, with more in the pipeline.

Through a personalized patient approach, MGB has a tracked consent rate of 93%. Patients are followed throughout their treatment, achieving serial unbiased collection of samples. Protocols are continuously updated, based on the current standard of care and best practices. Biospecimens are collected from multiple time points in the patient's treatment, along with associated clinical data. Consent and refusal rates, as well as withdrawal rates, are tracked using an electronic form, linked to the participant database.

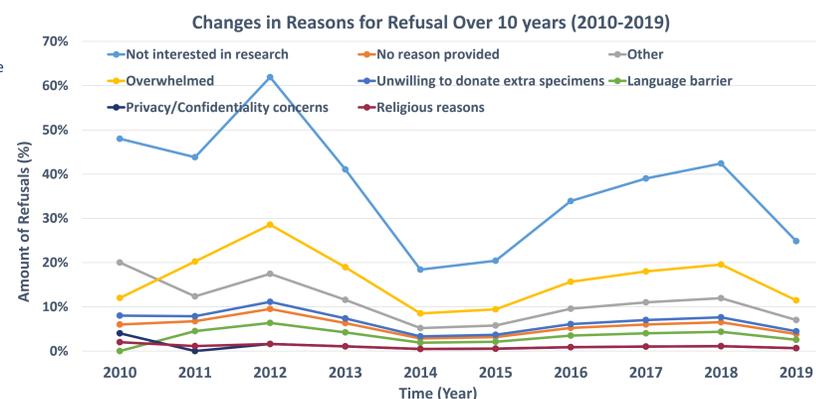
### RESULTS

Figure 3 – Reasons for Refusal: Common reasons for refusal among potential participants include: a lack of interest in participation in research initiatives, privacy or confidentiality concerns and reluctance to donate additional specimens. 18% of individuals who refused did not provide a reason for their decision



Approximately 10% of individuals refer to be overwhelmed due to illness and/or treatment when approached by biobank personnel. A "four-time approach" has been implemented to ensure individuals are given the option to be re-approached at a later time. The number of approaches is being tracked using an electronic form.

Figure 4 – Change in Participants' Reasons for Refusal Over Time: An analysis of the consent rate was done from 2010-2019, to assess the reasons behind participants' decisions for refusal to participate in the biorepository. Overall, the rationales for refusals have stayed relatively constant through the last 10 years.



Although the top reason for refusal: "No interest in participating in research" continues to be present, there has been a significant (17%) decline as compared to the previous year. The increase in interest in participating in research is likely due to the enhancement of participant engagement initiatives and marketing strategies, such as: focusing on updating the website, patient brochures, social media campaigns as well as the enhanced communication strategies with stakeholders and patient advocacy groups.

There has been a notable increase (3%) in refusals due to privacy and/or confidentiality concerns in the last few years. Efforts have been put in place with changes in the language utilized in the consent form and extensive training to staff pertaining to clarification of academic and non-academic collaborations, commercialization of samples and strategies in place to protect personal patient information.

### LESSONS LEARNED AND FUTURE DIRECTIONS

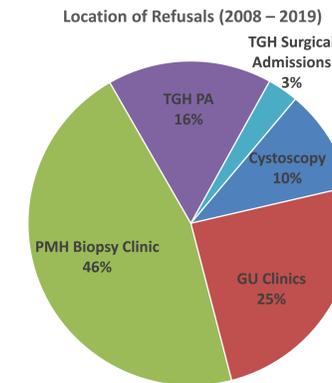


Figure 5 – Refusals to participate by location: Currently, MGB approaches potential participants in 10 genito-urinary oncology clinics across 3 different sites.

The majority of refusals take place in the Biopsy clinic as patients are approached prior to undergoing an invasive procedure. It is possible these high rates can be linked to the patient being overwhelmed. Further investigation to assess if there is correlation between these factors is underway.

The McCain GU BioBank has expanded over the last few years to include additional cancer sites, such as Gynecologic Oncology and Thoracic Oncology. A similar method to track patient approaches, consents and refusals will be implemented for these cohorts.

Assessment of factors such as: clinic location where participant is being approached, impact of procedure(s) in consent/refusal, tracking of number of approaches when undecided or not ready to provide a response, among other factors, have recently been implemented into tracker.

Participant and community engagement strategies continue to be a main focus of the McCain GU BioBank's business plan and marketing approach. Further assessment into the impact of such strategies into the consent/refusal rate will take place in the near future.

### CONCLUSIONS

- The growth in privacy/confidentiality and commercialization concerns by participants reflects a need to change our perspective and implement strategies as a biorepository in order to keep up to date with the industry and patient needs.
- By incorporating new metrics for the rate of participant consents versus refusals and optimizing the informed consent form, the McCain GU BioBank hopes to increase its consent rate further and remain an industry leader in uro-oncological biospecimens.

### REFERENCES

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