

### BACKGROUND



- At Moffitt Cancer Center, we created the Non-Therapeutic Research Office (NTR) in 2021 to provide centralized support for our non-therapeutic research (NTR) portfolio, comprised of >690 studies currently.
- NCI-designated Comprehensive Cancer Centers are expected to assess feasibility for interventional studies prior to moving forward in the activation process.
- A subset of Moffitt's NTR portfolio are interventional in nature and those studies had historically been reviewed (prior to NTR) by our only existing feasibility committee at the time, which was clinical trials focused. Notably, non-therapeutic intervention studies need specialized review as they frequently have different barriers to implementation (e.g., community participation) than therapeutic clinical trials.
- Thus, in order to provide expert, comprehensive feasibility review of NTR projects, the NTR Feasibility Committee was formed and staffed with faculty members that have extensive experience conducting these studies at Moffitt.

### GOALS

The goal was to create an NTR Feasibility Committee with appropriate representation to assess the feasibility of non-therapeutic interventional studies to ensure study success.

- The intention was to better facilitate timely review by faculty from diverse academic/clinical programs with subject matter expertise in NTR and to free up resources for the existing committee to focus only on treatment trials
- In the institutional feasibility committee, they reviewed the following interventional studies: 2023- 84; 2024-159.
- By convening separate committees and allowing each committee to concentrate on their areas of expertise, we aimed to assure feasibility for these specialized studies and improve activation times for all protocols.

### SOLUTIONS AND METHODS

A charter was developed to support the charge of the committee by NTR and to closely mirror the existing approach used by the institutional feasibility committee to ensure standardization of process, where applicable.

The committee completed the following:

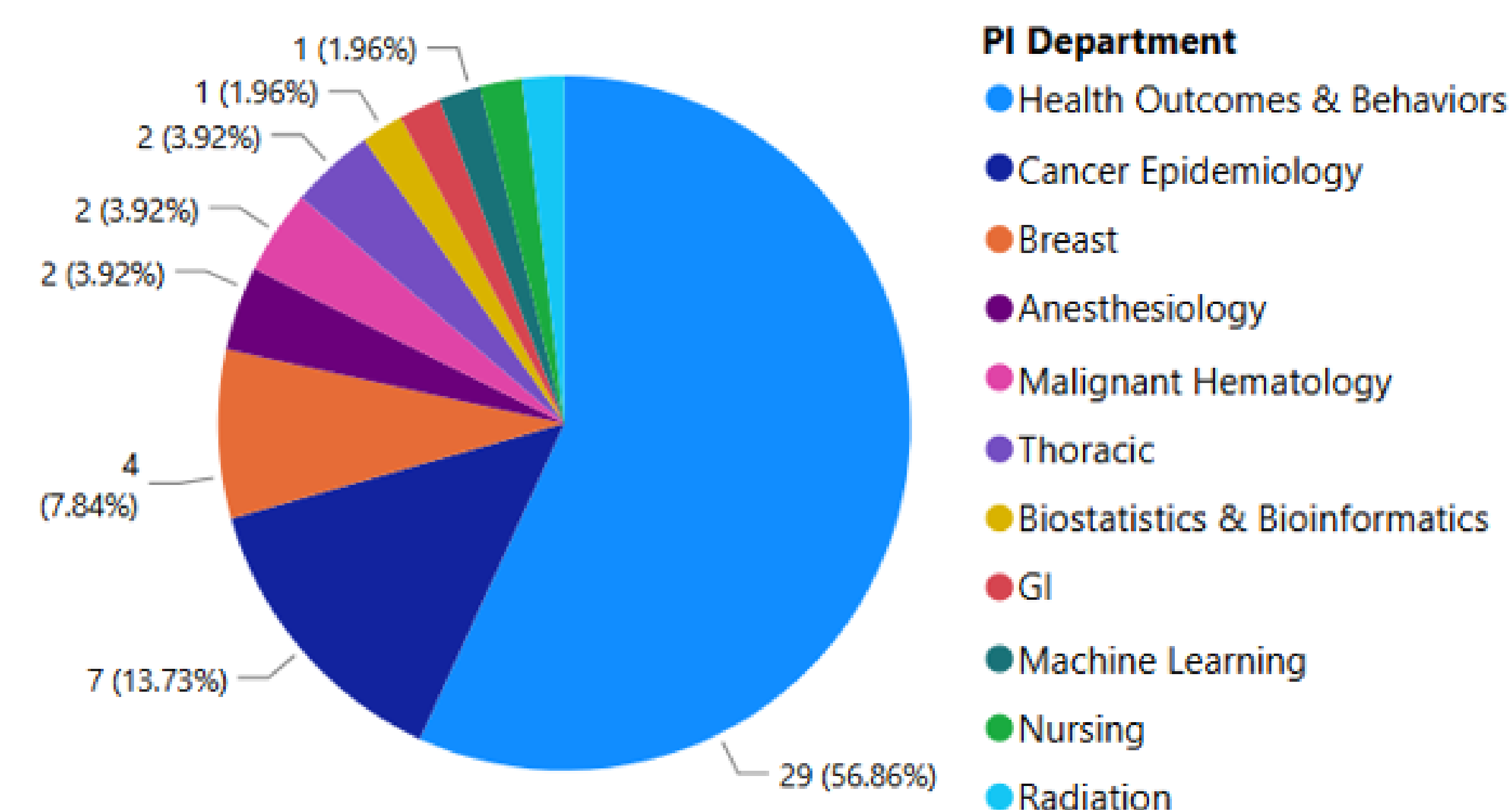
- 1) identified two co-chairs willing to lead the committee,
- 2) defined the voting quorum parameters,
- 3) invited a multidisciplinary group of faculty to participate as voting committee members, and
- 4) included non-voting operations leaders from key stakeholder departments supporting NTR studies.

### OUTCOMES

#### NTR Feasibility Committee: Studies Reviewed by FY

FY	Number of Studies
2023	7
2024	20
2025	24
Total	51

- The NTR Feasibility Committee meets 2X monthly and has reviewed 51 studies since our inaugural committee meeting in February 2023.
- Committee determinations include:
  - 44 Approvals
  - 4 Response Required
  - 3 Denied
- All studies not receiving approval initially were re-reviewed and subsequently approved based on incorporation of Committee feedback.



The timeframe for this graphic is from the inception of the committee until present (February 2023-present).

#### Types of Non-Therapeutic Interventions



### ROLES AND RESPONSIBILITIES

	Role Type	Brief Description
Administrative Assistant	Administrative	<ul style="list-style-type: none"> <li>Verify quorum prior to scheduled meeting</li> <li>Prepare agenda emails including read-ahead materials</li> <li>Prepare meeting minutes for review by co-chairs</li> </ul>
NTR Activation Coordinator	Administrative	<ul style="list-style-type: none"> <li>Intake &amp; review new submissions</li> <li>Maintain REDCap forms and database design</li> <li>Liaise w/ Regulatory Specialist</li> <li>Send out formal decisions from REDCap</li> </ul>
NTR Operations Manager & Director	Advisory	<ul style="list-style-type: none"> <li>Review new submissions &amp; oversight of NTR team</li> <li>Logistics &amp; planning in response to needs/concerns.</li> <li>Florence signatory on NTR Feasibility Form</li> </ul>
Other Operations Depts. (e.g., Tissue Core)	Advisory	<ul style="list-style-type: none"> <li>Review new submissions, advise on considerations, logistics &amp; planning</li> </ul>
Faculty Cmte Members	Voting & Advisory	<ul style="list-style-type: none"> <li>Formal voting members</li> <li>Review new submissions, advise on considerations, logistics &amp; planning</li> </ul>

### LESSONS LEARNED

- NTR was well poised to design and implement this committee.
- The faculty that comprise this committee have the needed expertise to review and comment on the protocols, and the NTR leadership have well supported the committee so that it runs in a very smooth and efficient manner.
- It is important to have an audience of faculty in this committee that understand non-therapeutic work, and it takes the burden away from the treatment trial feasibility committee.
- This has resulted in lowering frustration for NTR study PIs since they are getting more comprehensive reviews from experts in their area.

*The NTR Feasibility Committee, dedicated to reviewing non-therapeutic studies, has effectively allowed the institutional Feasibility Committee to focus on increasing the number of treatment studies reviewed. This strategic collaboration not only expands the variety of studies available for our patients but also aligns with our institution's mission. We are committed to maintaining a rigorous review process for all studies, ensuring the highest standards are upheld. –Margi Brelsford, Manager of PRMS*

### ACKNOWLEDGEMENTS

Acknowledgements are due to our Senior Director, Kristie Moffett for supporting us well for this endeavor. Our co-chairs of the committee also deserve recognition; Drs. Christine Vinci and Amir Alishahi.