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Enhancing the Capture of Oncology Study Activity via Scientific Review and IRB Collaboration

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1. Background

The UFHCC Scientific Review and Monitoring Committee (SRMC) is charged with review of all prospective cancer research conducted at the University of Florida. To facilitate capture of these studies, changes to institutional communication and research culture were required. In 2017, the University of Florida's (UF) research leadership, endorsed and mandated use of the SRMC for applicable studies prior to Institutional Review Board (IRB) approval. Prior to this directive, studies routinely reviewed by the SRMC were only those submitted by the UFHCC Clinical Research Office (CRO); units outside of the CRO did not receive a formal review. Therefore, there was no singular quality control mechanism to assure initial and ongoing capture of cancer relevant research activity.

2. Goals

- Enhance capture of cancer research activity including subject accruals
- Improved tracking of trial status within the Clinical Trials Management System
- Augment communication between the SRMC, study teams, and IRB

3. Solutions and Methods

UFHCC leadership held stakeholder meetings with key leaders from UF's Division of Sponsored Programs and UF's Health Science Center Colleges to support and drive the change in institutional review of cancer research. In summer 2017, UF's Vice President (VP) for Research and Senior VP for Health Affairs released a memorandum outlining the SRMC review requirement for all cancer research and enhancements to the IRB submission system to include a review trigger for SRMC. The memorandum also outlined that cancer relevant studies could not be IRB approved without SRMC approval.

To accomplish this, the IRB created a SRMC Oncology page with specific questions used to determine cancer relevancy. This page is deployed for all new and amendment submissions to the IRB. This facilitates the capture of both new and previously IRB approved studies. Contextual definitions and hyperlinks were added to educate study teams and email communication techniques were engineered to ensure timely SRMC reviews and responses.

Below are the cancer relevancy questions that are used to trigger a SRMC review:

- Study specifies enrolling patients with a known or suspected diagnosis of cancer as part of the eligibility criteria; or
- Includes research endpoints related to cancer, associated symptoms or established cancer risk factors (including smoking and tobacco-associated studies, surveys, hepatitis or HPV vaccines, etc.); or
- The local PI plans to exclusively enroll current, former or potential cancer patients into the study

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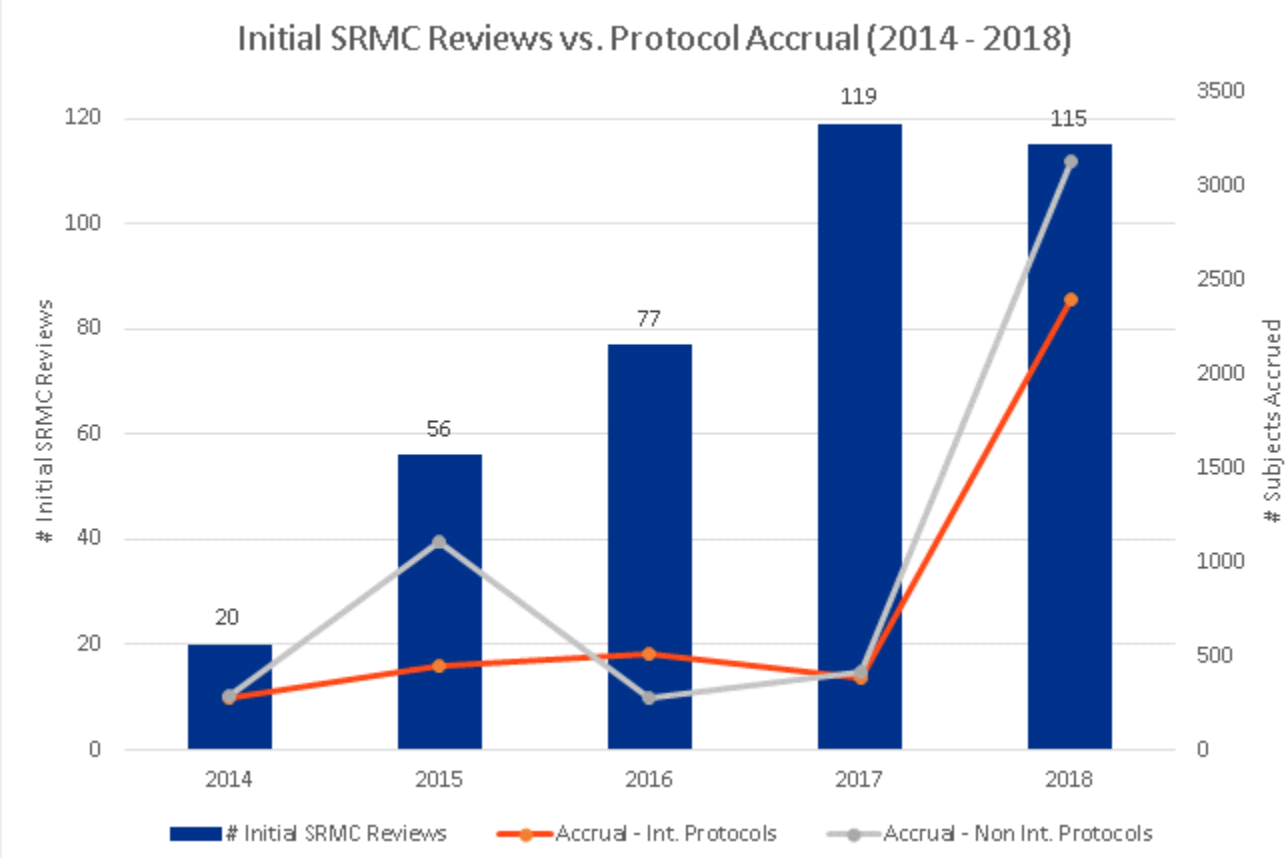
4. Outcomes and Future Directions

Prior to the interface, there was not one single mechanism to capture all cancer research studies conducted on campus, especially trials non-interventional in design. With the interface, the SRMC is now made aware of all studies identified as cancer-relevant at the time of IRB submission. Ultimately, this interface has supported tracking of accruals, status updates and/or study closures submitted for IRB review.



The number of studies requiring SRMC review proved to be much higher than projected; myriad of divisions (some previously unanticipated) and variations of studies were noted across campus. Moving forward, quarterly meetings with SRMC administrators and IRB leadership will be held to finesse the review processes. Additional enhancements to capture studies outside of study team initiated IRB submissions will also be explored.