

Streamlining Feasibility Assessment Within the Scientific Review Process

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1. Background

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) is committed to facilitating the conduct of clinical trials that are feasible, scientifically meritorious and ethically sound. To minimize activation of trials that will poorly perform and encumber significant resources (personnel, financial, material), the CRO Feasibility Group (FG) was created. The FG review includes assessment of tumor registry and clinical records for enrollment within similar patient populations. The success of the group was seen as fewer trials have been terminated due to low accrual by the Scientific Review and Monitoring Committee (SRMC) since the group's inception.

For interventional trials utilizing CRO resources, the FG review was built into the protocol activation process. However, this review did not extend to all research groups on campus. Additionally, the FG was a separate committee with specific submission deadlines for review. To combat investigator frustrations related to delayed processing, confirm compliance with the updated CCSG guidelines and ensure comprehensive review of the UFHCC interventional trial portfolio with a focus on catchment area impact, a streamlined review was established.

2. Goals

- Minimize logistical barriers to rapid study activation;
- Standardize feasibility review across all research units to minimize study termination due to low accrual

3. Solutions and Methods

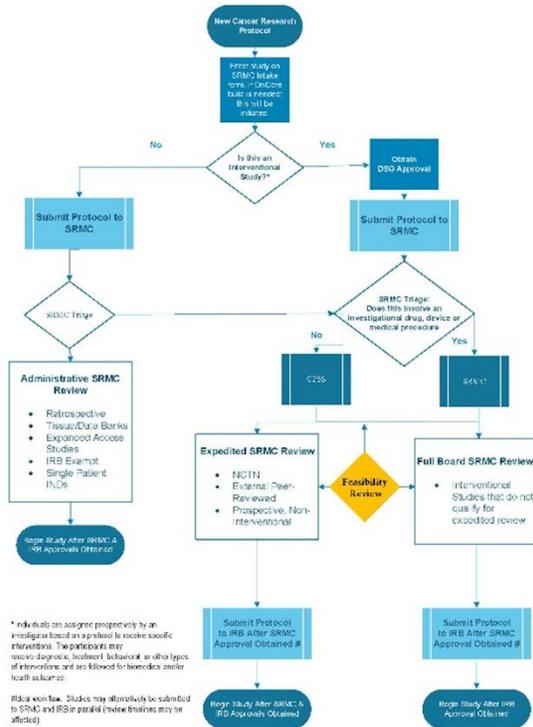
In early 2020, a combined review process was created that allowed feasibility review to be incorporated into the SRMC workflow for all interventional trials. Dynamic discussions were held between UFHCC CRO administration and SRMC leadership to map out the review process. As part of the initial SRMC review process, the feasibility review component provides non-binding recommendations, which ultimately are taken into consideration during the final SRMC determination vote. Feasibility review focuses on trial logistics and subject availability. A feasibility re-assessment is also conducted at continuation reviews for trials that do not meet local accrual targets. This review helps ensure the projected goal is reasonable based on current patient volumes and provides recommendations for recruitment resources.

The SRMC administrative team utilizes a Clinical Trials Management System (OnCore) for tracking and meets regularly to ensure all reviewer comments and reviews are received and responded to in a timely fashion. All SRMC Full Committee reviews require reviewer comments within 7 (non-IIT) to 14 (IITs) days; expedited SRMC reviews are to be received within 72 hours of submission. These expectations were initially viewed as laborious; however, with dedicated CRO staff conducting the feasibility reviews, this innovative review process has proven successful.

4. Outcomes

The collaboration resulting from these combined reviews have strengthened the interactions throughout the CRO and research teams. Ongoing discussions will continue in order to enhance the data collection and review process.

Metrics are pulled on a semi-annual basis to determine review and activation timelines related to how long it takes a trial to officially open to accrual as well as assessing subject enrollment and encompassing catchment area.



5. Lessons Learned

This innovative approach to comprehensive review is still relatively new. As the number of trials reviewed increases, a deeper dive into metrics and relationship to our research portfolios is expected to develop.