

Establishment of a Zero Tolerance Policy to Eliminate Non-Performing Studies

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1. Background

The UFHCC Scientific Review and Monitoring Committee (SRMC) is tasked with review of cancer relevant research studies conducted at the University of Florida (UF). The UFHCC Clinical Research Office (CRO) is primarily responsible for ensuring accurate protocol and accrual status entry within the Clinical Trials Management System (CTMS), OnCore, and notifying investigators of studies that are failing to meet minimum accrual benchmarks. Investigators and/or Disease Site Groups (DSGs) have long struggled with finding a balance between interesting science and feasibility of accrual resulting in portfolios that are misaligned with their patient population. The tax of resources to maintain trials (staffing, IRB support, contractual work, etc.) at a large academic cancer center, requires continuous review to ensure appropriate stewardship of limited resources. Evaluation of historic data illustrates that studies which fail to accrue within the first six months of site activation are unlikely to reach a successful completion.

2. Goals

- Closure of non-performing trials to allow for re-deployment of assigned resources
- Robust deliberations for trial selection within DSG portfolios, focusing on current patient needs and feasibility of trials

3. Solutions and Methods

In 2018, the SRMC developed the Zero Tolerance Policy to target interventional trials with no accrual activity. The initial implementation of the policy called for closure of a study if there were no patient accruals by 12 months post-activation. This policy was subsequently strengthened, placing studies on administrative probation at 3 months and requiring termination at 6 months if accrual remains at zero. As part of the probation process, the study undergoes a new feasibility review to determine if the appropriate patient population exists and if new recruitment strategies could be implemented. Investigators are also required to craft a Corrective Action Plan based on the feasibility findings. If the corrective actions fail, studies are administratively terminated by the SRMC if they are not electively closed by the investigator or DSG.

Exceptions to this policy include studies involving a rare disease (modified NIH definition), pediatrics, highly-selected IITs and studies experiencing moderate, but temporary, closures to accrual.

4. Outcomes and Future Directions

In 2018, implementation of the Zero Tolerance Policy resulted in a higher percentage of studies placed on probation compared to 2017 (37% vs 20%). Ultimately, the number of studies closed with zero accrual in 2018 rose by 30% over the previous year. Due in part to this policy, the initial feasibility review process has become more robust and data driven. The CRO has since established metrics used to assess available patients in light of investigator stated accrual goals. The ratio of available patients to target

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accrual is now a key part of the feasibility review process. Clear expectations for early study enrollment is now pervasive across the UFHCC.

Future directions include incorporating the UFHCC Community Outreach and Engagement (COE) director in initial and probationary reviews of trials to determine if there are opportunities to enhance recruitment via COE resources.