MEMORANDUM

DATE: October 25, 2017

TO: Investigators and staff involved in cancer-relevant research

FROM: Alison Ivey, RN  
Alison Ivey  
UF Health Cancer Center CTO  
Administrative Director

Thomas George, MD  
UF Health Cancer Center  
Associate Director for Clinical Investigation

RE: Scientific Review and Monitoring Committee intake policy for IRB approved studies

The Scientific Review and Monitoring Committee (SRMC) is responsible for the review of all cancer-relevant studies (including but not limited to retrospective, observational, ancillary/correlative, and interventional) conducted at the University of Florida. Effective July 20, 2017 all new studies that are considered cancer-relevant must be reviewed and approved by the SRMC prior to obtaining final IRB approval. Studies that were IRB approved prior to this date will still require initial SRMC review however, the level of review will be limited to administrative or expedited per the table below. The submission documents noted as being required for each study type within the SRMC Policies and Procedures manual are still required. Full scientific review will not occur for these existing studies that are already IRB-approved and enrolling patients. However, annual accrual monitoring and submissions of protocol revisions will still be conducted per the SRMC Policies and Procedures following initial review and approval.

<table>
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<tr>
<th>Study Type</th>
<th>Regular Review Level</th>
<th>Policy Exemption Level</th>
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| • UF Interventional Investigator Initiated Trial  
  • Industry, External Academic or Foundation Interventional Trials (non-external peer-reviewed) | Full | Expedited |
| • National Clinical Trials Network Trials  
  • External Peer-Reviewed Trials (NCI approved groups)  
  • Prospective, Non-Interventional Studies | Expedited | Expedited |
| • Retrospective, Non-Interventional studies  
  • Studies that meet criteria for IRB exempt status  
  • Single patient INDs  
  • Any cancer-relevant study that is permanently closed to accrual | Administrative | Administrative |

This policy exemption applies to initial SRMC approval only and was effective as of August 2017. Additional clarifications regarding documents required prior to review of IRB approved studies have been incorporated into this policy with this update.