Category: Regulatory – Completed Project

SOP Implementation for Managing CIRB studies in Data Analysis Only Status

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1. Background

The NCI CIRB does not have a policy or clear guidance for including institutional boilerplate language into amended consent forms for studies closed to accrual (CA) with all subjects off study. Our local IRB considers these studies to be in data analysis only status and does not require consent form updates for a study at this stage of IRB review. Furthermore, the resources required to include institutional boilerplate language into consent forms for use solely at the time of audit did not represent the best use of our staff resources.

2. Goals

Our goal was to develop a policy that would be accepted by the National Clinical Trials Network (NCTN) Groups at the time of audit for studies reviewed by the NCI CIRB. The policy would be provided during an audit in lieu of expending resources to add institutional boilerplate language to amended consent forms when studies were CA with all subjects off study.

3. Solutions and Methods

A helpdesk query was sent to NCI CIRB in October 2017 requesting the CIRB's policy on updating consents for studies closed to accrual with all subjects off study. The CIRB responded to the query in December 2017 stating it did not have a policy with respect to updating amendments for studies that are CA with all subjects deceased. The CIRB indicated we should follow our local policies regarding this matter. Our local IRB was consulted in January 2018 requesting its policy. The local policy stated our IRB would not accept amendments to informed consent documents as they would not have an impact where no living subjects are on study and the study is CA. After reviewing the CIRB and local IRB policies, an institutional SOP was written in May 2018 stating that CIRB trials CA with all subjects off study (in "data analysis only" by local IRB standards), will not be required to amend informed consent or HIPAA authorization documents. Late onset risk updates that may impact subject safety will be reviewed on a case-by-case basis. Other study documents will continue to be downloaded and stored in accordance to IUSCC CTO Regulatory SOPs and guidance documents. If a study is re-opened the study coordinator needs to verify the most current protocol is approved. If not approved, the study coordinator needs to submit the amendment to the regulatory team for IRB approval.

4. Outcomes and Future Directions

The site was cited in an NRG audit in February 2019 for not incorporating amendment changes or boilerplate language into the informed consent for a study closed to accrual with all subjects off study. The "Managing CIRB Amendments in Closed to Accrual Trials with all Subjects Off-Study" SOP was provided to the auditors in the audit response. The auditor queried the site asking if the site participated in the optional imaging sub-study. The site responded indicating it did not. The auditor removed the citations regarding incorporation of amendment and boilerplate language requirements from the final

audit report. An SOP for termination of studies open for data queries and application to basket and umbrella trials is being explored.