SOP Implementation for Incorporation of Amendments and Local Boilerplate Language for CIRB studies in Data Analysis Only Status

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Background

The NCI Central Institutional Review Board (CIRB) does not have a policy or clear guidance for including institutional boilerplate language into amended consent forms for studies closed to accrual 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 that would only be used at the time of audit did not represent the best use of our staff resources.**

Goals

1. **Develop a policy that would be accepted by the National Clinical Trials Network (NCTN) Groups (ECOG, NRG etc.) at the time of audit for studies reviewed by the NCI CIRB**
2. **Provide the policy at the time of audit in lieu of using resources to add institutional boilerplate language to amended consent forms when studies were closed to accrual with all subjects off study.**

Solutions and Methods

Help Desk Query Submitted to NCI CIRB

- Requested CIRB's policy on updating consent forms for studies closed to accrual with all subjects off study
- CIRB stated it had no policy and that local policies should be followed

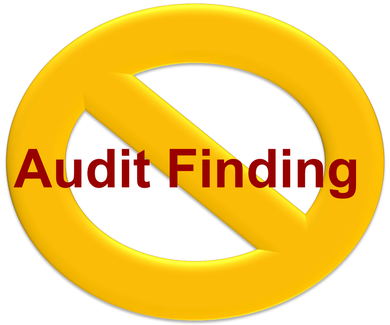
Local IRB Consulted

- The local IRB's policy stated it 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 closed to accrual

Institutional SOP Written

- SOP states CIRB trials closed to accrual 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….Other study documents will continue to be downloaded and stored in accordance with IUSCC CTO Regulatory SOPs and guidance documents.

Outcome



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.

Lessons Learned

Establishing an SOP for incorporation of institutional boilerplate language saved time and resources

Future Direction

The site would like to apply the policy to include basket trials and umbrella trials that have a screening protocol requiring subjects to be positive for a genetic variant. These trials can have numerous consent forms and amendments without ever accruing a subject. Using a "just in time" approach for these sub studies and only updating consent forms for arms that have a subject accrued will be explored. An SOP for termination of studies open for data queries and application to basket and umbrella trials is being explored.

References

NCI CIRB SOPs https://www.ncicirb.org/about-cirb/sops.
IU IRB SOPs https://research.iu.edu/policies/human-subjects-irb/irb-review-process.html

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