Multicenter Investigator-Initiated Trial Prioritization

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1. Background

No process existed previously to determine what infrastructure would support institutional multicenter investigator-initiated trials (IIT) at Indiana University (IU). It was unclear to Sponsor-Investigators who would manage their multicenter IIT, the IU Simon Cancer Center (IUSCC) Multicenter infrastructure or an outside contract research organization (CRO). A clear guideline was also needed to prioritize use of the multicenter infrastructure to appropriately allocate resources to high priority trials.

2. Goals

The IUSCC Clinical Trials Office set out to establish a process and decision tree to assist Sponsor-Investigators in identifying the appropriate infrastructure to manage an institutional multicenter IIT. Criteria considered in the decision tree included:

- Funding source
- Number of participating sites
- Geographical location of sites
- Support by Cancer Center

3. Solutions and Methods

An SOP was established utilizing a clear process and well-defined criteria to determine when the IUSCC Multicenter infrastructure would be employed and when the IIT would be referred to an outside CRO. A process was instituted whereby institutional studies proposing to be opened through the Multicenter infrastructure required review and approval by the Administrator for Quality and Education, the IUSCC Associate Director or Clinical Research and if applicable, Cancer Center leadership. This process also incorporated discussion of the funding support for multicenter infrastructure. Sponsor-investigators were made aware that a percent effort of the budget may be required to support multicenter infrastructure if a protocol was approved for multicenter management by the institution.

4. Outcomes and Future Directions

Since execution of the SOP in February 2018, 6 studies have been opened using this process and have been successfully managed by the IUSCC multicenter team. This has provided Sponsor-Investigators and the institution with clear direction and guidelines when considering and opening institutional multicenter IITs. For example, the addition of international participating sites was requested by two Sponsor-Investigators. These requests were denied based on the SOP. A study without funding to support multicenter infrastructure was submitted to the Cancer Center leadership and was successful in obtaining leadership support to open as an institutional multicenter IIT.

While progress has been made in the decision process for institutional management of multicenter IITs, there are additional areas for growth and policy refinement. A process needs to be established for situations in which a study is opened under IUSCC Multicenter management but then exceeds the site criteria in the SOP. Three options can be considered in this situation. The IUSCC multicenter infrastructure can agree to manage the additional sites, reject the addition of new sites or transfer management of the study to an outside CRO. Other complications that have surfaced include the Sponsor-Investigators reaching out to a CRO for management and bypassing the process outlined in the SOP. This is primarily due to lack of understanding of this process by the Sponsor-Investigator. The Multicenter team will investigate additional collaboration with Indiana University's outside CRO partners to educate on this process. Additionally, providing the Multicenter IIT Prioritization SOP to Sponsor-Investigators earlier in the protocol development process as well as incorporating review of the SOP during new faculty orientation can aid in education.