Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Streamlining minimal risk studies: creating a request process, comprehensive database, and governance structure

J. Laeng, B. Matia, M. Rump

Cleveland Clinic Cancer Center

1. Background

Due to a lack of standardized processes, minimal risk study submissions have been a source of confusion, inefficiencies and frustration for research coordinators, principal investigators (PIs), database managers and the institutional review board (IRB). Additionally, there is an opportunity to improve the centralized governance and escalation regarding the compliance of minimal risk studies.

2. Goals

Streamline the process for minimal risk studies:

- Create a formal submission process for investigators to submit their studies
    - Improves efficiencies and reduces email communications
- Create a comprehensive data base of all minimal risk studies
    - Allows for a way to track all minimal risk process
    - Provides a mean to check for overlapping projects and/or data collection efforts
- Provide centralized oversight and governance of minimal risk projects with clear escalation and approval mechanisms

3. Solutions and Methods

Process: A REDCap survey has been developed to streamline project intake by gathering key information such as funding sources, data variables and protocol details. This form is completed by the investigator and/or study team to ensure the project is organized appropriately and has all necessary approvals. This streamlined and proactive approach minimizes delays, prevents duplication of efforts and reduces coordinator time.

This survey will serve as a trigger for the intake team to:

- Notify relevant stakeholders of new projects (i.e. medical scientific writer, database developers, genomics program)
- Facilitate the assignment of research coordinators to individual projects
- Ensure all necessary approvals and funding are in place

These surveys will then feed into a comprehensive database that can be utilized to identify overlapping projects and/or data collection and will aim to provide administration with insight on research coordinator metrics based on study assignment.

Governance: This survey will also serve as a mechanism to collect all necessary approvals (Disease Team Program Director, etc.) and documentation of funding. By standardizing the request and approval processes, we are able to create and enforce a governance and escalation framework.

4. Outcomes

We plan to roll this survey and process out in the next few months.

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5. Lessons Learned and Future Directions

A future goal of this project is to also incorporate quality improvement decision tree to capture an approval process regarding whether a project is a quality improvement versus human subjects research. This addition will align with the improved governance structure of these projects.