*Category: Regulatory - Work in Progress*

**Regulatory Burden of IRB Submissions: Commercial vs. Internal IRBs**

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**1. Background**

The University of Michigan (UM) Health Rogel Cancer Center's Oncology Clinical Trials Support Unit (O-CTSU) primarily has utilized UM's internal IRBMED as the institutional review board (IRB) for industry studies. In second quarter of 2021, a pilot was instituted to increase the utilization of central institutional review boards (cIRB), such as Advarra and WCG, to reduce approval and study activation timelines.

O-CTSU's Regulatory team is separated into two units: Start-up (focus on coordination through initial IRB approval) and Maintenance (focus on coordination after initial approval). The Regulatory team standardized the utilization of IRBMED across the entire portfolio of studies with established guidelines and reporting requirements. In addition, O-CTSU and IRBMED have a collaborative feedback loop in place to address changes, issues, and questions that arise. In comparison, use of cIRBs for O-CTSU was low and without standardized processes. Further, IRBMED does not cede oversight of all aspects of trials and institutional ancillary committees remain linked to the IRBMED application, resulting in duplicative submissions in IRBMED and cIRB systems. While IRB approval and activation timelines showed an improvement, the O-CTSU Regulatory team expressed an increase in effort and resources spent on managing cIRB studies.

**2. Goals**

- Determine the regulatory effort of utilizing cIRB compared to IRBMED for industry studies

**3. Solutions and Methods**

Due to our staff recording effort in a web-based research effort tracking application (RETA), we were able to determine the amount of time spent on specific tasks over a standard time frame. We included studies with amendments, other reportable information or occurrence (ORIOs), and continuing renewals. This yielded 41 IRBMED studies and 41 cIRB ceded studies for analysis. For each study, we separated the tasks into Start-up and Maintenance focused. For each category we evaluated total, median, and average time.

**4. Outcomes**

Upon analysis, the initial application with cIRBs required 32.4 percent less effort on average, with substantial time savings captured in the ICF development and revisions/contingencies. Once the study was transferred to Maintenance, the effort increased for cIRB studies compared to IRBMED studies. On average, a Maintenance RC uses an increased effort of 3.4 percent per protocol amendment, 42 percent per non-protocol amendment, and 3.3 percent per ORIO. The biggest increase in effort was spent on approval notifications and distributions with cIRB studies taking on average an additional 39 percent longer per study to process.

**5. Lessons Learned and Future Directions**

While the initial application for cIRB studies requires less time, due to a shorter internal application to IRBMED for ceded studies, the overall effort is higher in the maintenance phase. This could be due to our institution still requiring ancillary committee reviews prior to implementation of amendments,

unfamiliarity with cIRB web platforms, or lack of a close working relationship with cIRBs. Additional data and time are needed to evaluate why there is an increase in maintenance effort for cIRB studies. We want to evaluate this same group of studies during their lifetime at our institution and compare the time saved at start up to the effort increase in maintenance to help inform our finance team adjust budgets more appropriately.

**Figure**