Regulatory Burden of IRB Submissions: Commercial vs. Internal IRBs

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Background
The University of Michigan 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
- Maintenance: focus on coordination after initial approval through termination

The Regulatory team consists of 1 manager, 3 leads, 1 project coordinator/administrator, 5 start-up coordinators and 10 maintenance coordinators. The team supports over 400 projects at any given time.

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 minimal and without standardized processes. Furthermore, when using a cIRB, IRBMED does not cede oversight of all aspects of trials and institutional ancillary committees remain linked to the IRBMED application, thus 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 being spent on managing cIRB studies. Our staff records effort in a web-based research effort tracking application (RETA). We were able to use RETA tracking to determine the amount of time spent on specific tasks over a standard time frame. We included studies with amendments, other reportable information or occurrences (DROIs), 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.

Methods
Our staff records effort in a web-based research effort tracking application (RETA). We were able to use RETA tracking to determine the amount of time spent on specific tasks over a standard time frame. We included studies with amendments, other reportable information or occurrences (DROIs), 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.

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

IRBMED Regulatory Amendment Submission Process

Commercial IRB and IRBMED Regulatory Amendment Submission Process

Discussion
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. While there may be a savings in Start-up as this period can be a relatively short period compared to Maintenance. The difference between some values may appear to be small (e.g., 336 minutes vs. 468 minutes for AMD distributions), this is per event and would compound over time unless a change is made, as the maintenance phase is much longer.

This could be due to our institution still requiring ancillary committee reviews prior to study activation. There has been a change in our protocol that requires all clinical trials to go through a review by the cIRB, and this is expected to compound over time.

Future Directions
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 to adjust budgets more appropriately.

We want to break the studies down further to see if the phase and complexity of the cohorts under the protocol affects the time requirements.

Outcomes Cont.

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Average minutes per IRBMED Application, Other Amendment</th>
<th>Average minutes per cIRB Amendment</th>
<th>Average minutes per ORIO</th>
<th>Average minutes per IRB Approval Notifications &amp; Distribution event</th>
<th>Average minutes per IRBMED &amp; cIRB SCR &amp; Termination event</th>
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</thead>
<tbody>
<tr>
<td>Standard</td>
<td>528</td>
<td>114</td>
<td>54</td>
<td>336</td>
<td>72</td>
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<tr>
<td>cIRB</td>
<td>546</td>
<td>162</td>
<td>72</td>
<td>468</td>
<td>78</td>
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<tr>
<td>WCG</td>
<td>468</td>
<td>84</td>
<td>84</td>
<td>300</td>
<td>54</td>
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<tr>
<td>Advarra</td>
<td>642</td>
<td>234</td>
<td>60</td>
<td>492</td>
<td>90</td>
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</tbody>
</table>

Advarra

WCG

Average Time Spent

Once the study was transferred to Maintenance, the effort increased for cIRB studies compared to IRBMED studies. On average, a Maintenance Research Coordinator experienced an increased effort of 3.4% per protocol amendment, 42% per non-protocol amendment, and 3.3% per ORIO. The biggest increase in effort was spent on approval notifications and distributions, with cIRB studies taking on average an additional 39% longer per study to process.

Outcomes Cont.

<table>
<thead>
<tr>
<th>Type</th>
<th>Application, Other Amendment</th>
<th>Amendment</th>
<th>IRB/PRC</th>
<th>IRB SCR &amp; Terminations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>41</td>
<td>23</td>
<td>0.55</td>
<td>0.12</td>
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<tr>
<td>Average</td>
<td>28</td>
<td>12</td>
<td>0.44</td>
<td>0.1</td>
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</table>

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

Conclusion
Upon analysis, the initial application with cIRBs required 32.4% less effort on average with substantial time savings captured in the ICF development and revisions/contingencies.

Through the collaborative relationship with cIRBs, we are able to organize reviews more efficiently, which has resulted in a significant reduction in our effort. The effort required for cIRB studies is additive to that of the IRBMED studies for the initial submission, but the difference is offset by the reductions in maintenance.

Our team has been able to use the cIRB as a central coordination mechanism for all per protocol amendments and continue to study activation timelines.

Acknowledgments
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Michigan Medicine Oncology Clinical Trials Support Unit SC wishes to thank all of their tireless efforts and contributions to Oncology Clinical research.