Regulatory Burden of IRB Submissions: Commercial vs. Internal IRBs

ROGEL CANCER CENTER
UNIVERSITY OF MICHIGAN HEALTH

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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.

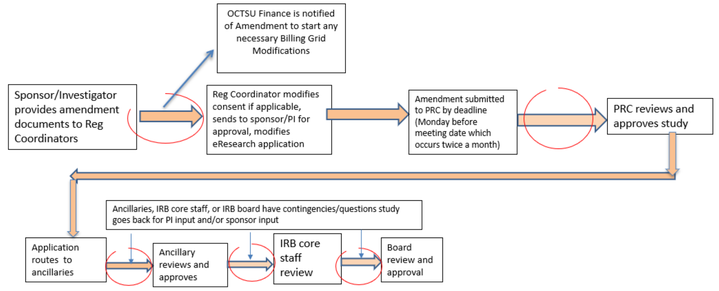
O-CTSU's Regulatory team is separated into two units:
- Start-Up- focus on coordination through initial IRB approval
- Maintenance - focus on coordination after initial approval through termination

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.

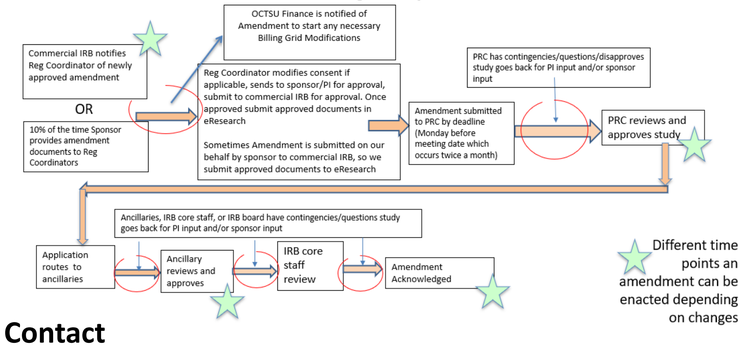
The Regulatory team standardized the utilization of IRBMED across the entire portfolio of studies with established guidelines and reporting requirements. In addition, O-CTSU and IRBMED have a collaborative feedback loop in place to address changes, issues, and questions that arise. In comparison, use 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.

IRBMED Regulatory Amendment Submission Process



Commercial IRB and IRBMED Regulatory Amendment Submission Process



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Goal

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

Methods

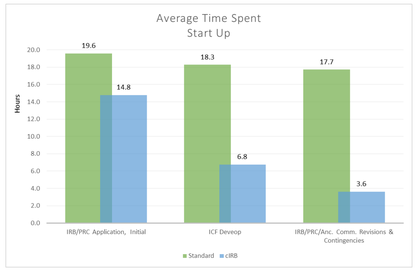
Our staff records effort in a web-based research effort tracking application (RETA). We were able to use RETA tracking to determine the amount of time spent on specific tasks over a standard time frame. We included studies with amendments, other reportable information or occurrences (ORIOs), and continuing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

RETA Effort Statistics
- Effort Record during a standard timeframe
- Reviewed the following Categories:
  - IRB/PRC Application
  - Initial ICF Develop
  - IRB/PRC Application, Protocol Amendment
  - IRB/PRC Application, Other Amendment
  - IRB/PRC/Anc. Comm. Revisions & Contingencies
  - IRB Application, ORIO
  - IRB Approval Notifications & Distribution
  - IRB SCR & Termination, eResearch

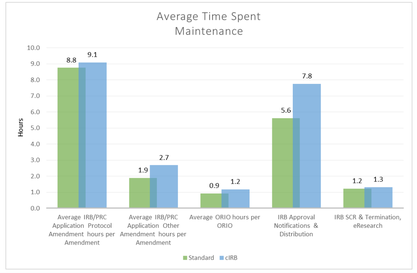
Application Type	Total Number Evaluated	Total # of Studies with Protocol Amendments	Total # of Studies with other Amendments	Total # of Studies with ORIOS	IRB SCR & Termination
Standard	41	20	28	12	14
cIRB	41 (Advarra- 23) (WCG- 18)	14 (Advarra- 8) (WCG- 6)	23 (Advarra-12) (WCG- 11)	6 (Advarra- 4) (WCG 2)	18 (Advarra- 10) (WCG- 8)

Outcomes

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.

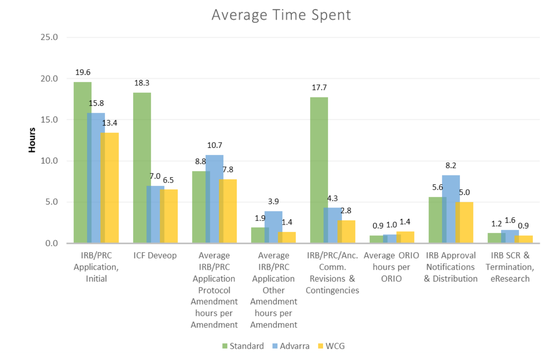


Once the study was transferred to Maintenance, the effort increased for cIRB studies compared to IRBMED studies. On average, a Maintenance Research Coordinator experienced an increased effort of 3.4% per protocol amendment, 42% per non-protocol amendment, and 3.3% per ORIO. The biggest increase in effort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



Outcomes Cont.

Application Type	Average minutes per IRB/PRC Application Protocol Amendment	Average minutes per IRB/PRC Application, Other Amendment	Average minutes per ORIO	Average minutes per IRB Approval Notifications & Distribution event	Average minutes per IRB SCR & Termination event
Standard	528	114	54	336	72
cIRB	546	162	72	468	78
WCG	468	84	84	300	54
Advarra	642	234	60	492	90



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 implementation of amendments, or unfamiliarity with cIRB web platforms, or lack of a close working relationship with cIRBs.

Additional data and time is needed to evaluate why there is an increase in maintenance effort for cIRB studies.

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.

Acknowledgments

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