Performance Metrics and Continuous Improvement

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University of Illinois College of Medicine at Peoria (UICOM-P) and its Office of Human Research Oversight (OHRO) enrolled with IRBNet and the National Research Network in Q1, 2008. Annual data were reported from 2009 activities. Snapshot:

- 2.8 FTE staff manage IRB activities at the OHRO
- 2 Institutional Review Boards
- 558 active projects as of 3/1/2010
- 2523 reviews (expedited, convened) recorded
- 2637 unique OHRO submissions managed
- 2737 letters issued by OHRO staff

RESEARCHER ACTIVITY

14 institutions conducted OHRO human subjects research; 4 of these dominated research site activities. Investigators consist of novice investigators as well as study coordinators managing 50 or more projects.

RESEARCH PROFILE

The portfolio is dominantly more than minimal risk and biomedical. Half are open to enrollment.
REVIEW ANALYSIS: EFFICIENCY GAINS, CONTINUOUS IMPROVEMENT

Analysis of granular review process data has resulted in a process of continuous improvement and clear communication with institutional stakeholders. Lean staffing, seasonality, and university calendars directly impact monthly results.

UICOMP outperforms national benchmarks, while managing greater average IRB workload.

Expedited reviews perform efficiently.
- Two IRB chairs and the OHRO Director process expedited reviews on a part time basis.
- 2009 Expedited Reviews: 2043
- Average time to decision: 14 calendar days.

Convened reviews perform efficiently.
- Average time to decision: 25 days.
- Number of 2009 Convened Reviews: 480
- Average time from decision to board letter: 3 calendar days.
RESOURCES
The Office of Human Research Oversight operates resource-efficiently as compared to nationally reported data.

- More Protocols managed per FTE.
- Less total budget allocated.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Protocol Category</th>
<th>Average Number of Staff</th>
<th>Average Number of Protocols</th>
<th>Average Protocol per FTE</th>
<th>Annual Budget for IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>UICOMP</td>
<td>558 (actual)</td>
<td>2.8 (actual)</td>
<td>558 (actual)</td>
<td>180 (actual)</td>
<td>SIGNIFICANTLY LESS</td>
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<tr>
<td>AAHRPP</td>
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<td>706</td>
<td>162</td>
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DISCUSSION, CHALLENGES AND SUGGESTIONS

STATEMENT OF THE IRB CHALLENGE
The complexity of IRB benchmarking is poignantly illustrated in the words of Dan Nelson, SACHRP’s Subpart A Subcommittee Co-Chair: “When you’ve seen one IRB…you’ve seen one IRB.”

Due to differing definitional interpretations across institutions, comparing IRBs is like comparing apples to oranges. As a result, prior published IRB Benchmark data is extremely limited, and offers little guidance for setting goals for timely turnaround of materials or metrics for quality improvement. In response, the UICOMP IRB in conjunction with IRBNet has developed a reporting mechanism for cycle time and portfolio analysis to manage IRB efficiencies. Since the implementation of IRBNet in April 2008, UICOMP has reliable data for all IRB activity.

DESCRIPTION OF PROGRAM
IRB data analyzed includes research portfolio characteristics, expedited and convened review cycle times (time to decision and letter), item type (ex. amendment, continuing review, UPIRSO, other, new studies, closure/final reports), workload and research community composition (novice vs power users).

FUTURE PROGRAM USAGE
The UICOMP IRB will continue to use these benchmarks for the management of IRB membership, PI and IRB member education, staffing decisions, time management, customer service and departmental budgeting. UICOMP intends to share this data with other IRBNet users in an effort to glean “best practices” from similarly organized HRPP programs.

SUGGESTIONS FOR OTHER SITES
Implementation of a database workflow system that can track reliable and consistent data empowers an institution striving for continuous quality improvement. Quantitative and qualitative analyses of IRB data is powerful evidence when making management decisions and/or arguments at a departmental or institutional level.
INSIGHTS FROM ANALYSIS

BOARD MEMBERS

• Board composition Analysis of research portfolio characteristics has led to reflection on appropriate board composition.

• Be conscious of social/behavioral components of biomedical studies such as QOL questionnaires when calculating % of social/behavioral research activity.

ADMINISTRATIVE IMPLICATIONS

• Early identification and planning for UICOMP calendar events and educational travel may minimize the impact of these situations on efficiencies (turn around time, etc.)

• Early identification of meeting dates (5 week months vs. 4 week months) and submission deadlines (variable during holiday months) may minimize the impact of these situations on time to decision/letter.

PROCESS REFINEMENTS

• Identify workload as precisely as possible in order to accurately gauge time commitment required for meaningful review: Identified need to increase choices for item type in IRBNet to delineate “other.”

• Be conscious of temporary “ballooning” of item types for review when gauging workload calculations for departmental budgeting (ex: one time Oncology staffing change activities; anticipated to sharply reduce.)

RESEARCH COMMUNITY EDUCATION

• Continuous human subjects training is warranted: Adverse Event submissions drop due to submission refinements and education of study coordinators.

• High percentage of novice investigators identifies priority for education of investigators.

• Further segmenting of novice investigators (ex. residents, medical and nursing students) enables tailoring of investigator education for maximum group benefit.