The Effect of Computer Automation on Institutional Review Board (IRB) Office Efficiency

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ABSTRACT

Companies purchase computer systems to make their processes more efficient through automation. Some academic medical centers (AMC) have purchased computer systems for their institutional review boards (IRB) to increase efficiency and compliance with regulations. IRB computer systems are expensive to purchase, deploy, and maintain. An AMC should expect a positive return on investment from the purchase of an IRB system. An IRB system should decrease the processing time for IRB applications and affect the number of IRB staff members necessary to adequately handle IRB processes. This study examined these and other factors at AMCs to determine the value of IRB computer systems.

INTRODUCTION

There is a lack of studies specific to the results of implementing a computer system to support IRBs. These systems are very expensive and challenging to implement. The rewards from this technology should be a more efficient operation that puts less of an administrative burden on the investigators utilizing IRB services. The outcome of this project provides evidence to indicate that larger IRBs are aided by computerized systems.

IRBs need to efficiently process protocol submissions. Delays in processing submissions are frustrating for both the investigators and the research sponsors. In fact, for several years there has been a movement towards using a centralized IRB rather than a local IRB (Weschsler, 2007). One of the reasons for this preference is that central IRBs are often quicker to process protocols than local IRBs (Weschler, 2007). This is particularly true with multi-center studies where a centralized IRB would

provide a single, more efficient review rather than multiple reviews by each local IRB associated with the project (Food and Drug Administration, 2011). A study conducted by Whitney et al. (2008) included a survey of principal investigators' (PI) views towards IRBs. Both negative and positive responses towards the IRB system were offered by the PIs. The negative responses portrayed the IRB process as a research burden—investigators perceived IRB processing of research protocols as being slow and inefficient. Andrews et al. (2012) described how a local IRB can be made more efficient without adding additional cost by workflow redesign. This workflow redesign was done without adding computer systems that undoubtedly would have increased the cost.

Computerized systems have been implemented in many industries in order to increase efficiency and eliminate process bottlenecks that can lead to employee or customer dissatisfaction. A few papers have outlined the success of implementing systems in research institutions to help track budgets and increase the productivity of the research administrative offices. The Medical University of South Carolina (MUSC) effectively implemented a web-based budgeting system (Glenn & Sampson, 2011). The Mayo Clinic increased the quality of the services offered by its research administration offices by implementing a new pre-award and IRB system (Smith & Gronseth, 2011). A study from the Imperial College of London described the implementation of both a pre-award and post-award system (Rutherford & Langley, 2007). All of these papers offer insights into the implementation of computer research administrative systems at a single institution. They all cite benefits of the new systems but are only focused on a "case study" regarding a particular institution's implementation of computerized systems. The studies lack the presentation of data from multiple institutions that supports the cost of purchasing and implementing new systems. Our study presents productivity data from multiple institutions that were used to inform the decision to acquire and implement an IRB computer system.

The *2012 Metrics on Human Research Protection Program Performance* report issued by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) indicated that 90% of AAHRPP-accredited institutions reported using a database to track IRB protocols, while only 40% of accredited institutions reported using an online system for the actual IRB review functions (AAHRPP, 2013). Additionally, the AAHRPP metrics showed that the "use of computer systems for the distribution of materials has increased consistently since 2009" (p. 15). A caveat to these statistics, however, is that the data come from institutions that meet the high standards for excellence in their Human Research Protection Programs required for AAHRPP accreditation. Therefore, these

data may not be applicable to all IRB programs in academic medical centers.

METHODS

This study design involved a cross sectional survey. Data were collected via a 12-item survey tool distributed to senior Institutional Review Board (IRB) administrators at institutions belonging to the University Health Consortium (UHC). The UHC is an organization comprised of 120 academic medical centers and 299 of their affiliated hospitals. The UHC mission is to facilitate performance improvement for member institutions. Of the 120 UHC-member AMCs, contact information for a senior IRB administrator was publicly available for 92 institutions. A senior IRB administrator was defined as an individual within the IRB office with a job title equivalent to manager or above. An email was sent to the 92 identified IRB administrators with a letter of introduction and a link to the survey in Google Docs®. Two weeks after the initial contact, a reminder email and link to the survey were sent to the same cohort of identified IRB administrators.

The survey was kept open for a total of four weeks from the initial point of contact to maximize response rates after each of the two contacts. Responses to survey questions were returned anonymously; however, respondents had the option to include contact information at the conclusion of the survey if they wished to receive a copy of the aggregate data as an incentive for participation.

All research activities were reviewed and approved by the Rush University Medical Center Institutional Review Board.

RESULTS

The data were analyzed for consistency and statistical significance using a standard statistical software package. Two survey responses were removed from the analyzed data set due to inconsistent responses. The two survey responses incorrectly stated or omitted the percentage of studies the organization sent to an external IRB for review. Table 1 provides the overall statistics for the survey, including the 41% response rate.

Table 1
Response Rate for Survey

Total Surveys Sent	92
Total Surveys Received	38
Response Rate	41.30435

Table 2 offers the descriptive statistics for the data collected via the survey. The vast majority of respondents have computer systems to help automate the IRB process.

Table 2
Descriptive Statistics for Survey Responses

Variable		N(%)
Computer System for IRB	Yes	29 (76)
	No	9 (24)
Institutions with External IRB	Yes	24 (63)
	No	14 (37)
AAHRPP Accreditation	Yes	27 (71)
	No	11 (29)
Variable		**Median (25th Percentile, 75th Percentile)**
Information Services FTE (with computer system)		1.5 (1, 3)
Total Number of Active Studies at the Institution		2100 (1275, 4000)
Number of IRBs		4 (2, 4.25)
Percent of Studies Sent to External IRB		5 (2, 13.75)
Variable		**Mean ± SD**
IRB Staff (FTE)		11.64 +/- 7.07
Percent Expedited Studies per Institution		57 +/- 18
Days to Process Expedited Studies		22.5 +/- 13.5
Percent of Studies Sent to Full IRB Board Review		30 (24, 40)
Days to Process Full Board Studies		40.2 +/- 20.1

Comparison of IRB FTEs vs. IRB Computer Systems

Figure 1 plots the mean IRB FTEs for organizations with and without a computerized IRB system. A one-way ANOVA was used to compare IRB FTEs for organizations with (12.224 ± 6.487, n=29) and without (9.778 ± 8.871, n=9) a computer system. The analysis indicates that there was no difference in the mean number of FTEs in organizations with or without a computer system ($F_{1,36} = 0.819$, p=0.372).

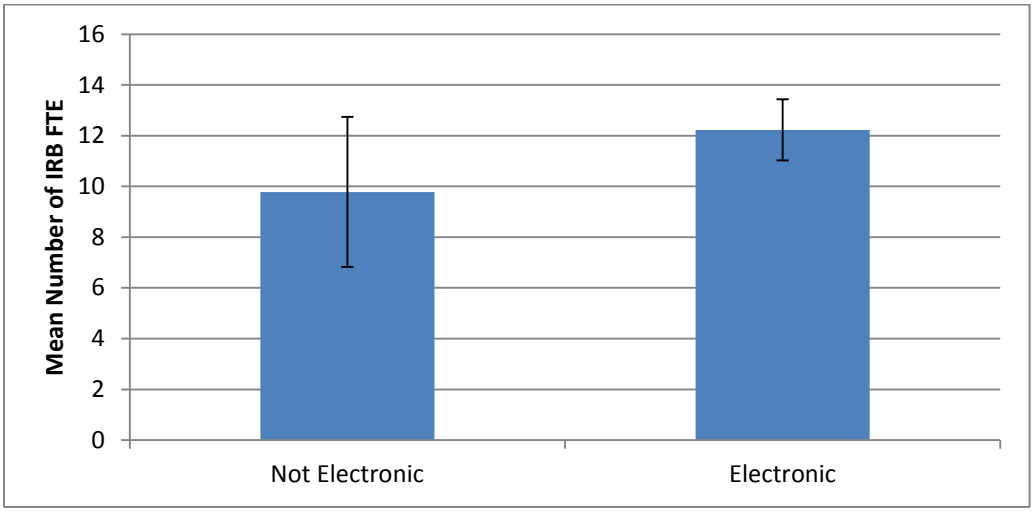

Figure 1. Number of IRB Full-Time Equivalents (FTE) on Organizations with and without a Computer System

Comparison of IRB FTEs vs. Number of Studies

A Spearman's correlation test was conducted on the data (see Figure 2). Test results indicated a statistically significant positive relationship between IRB FTEs and number of studies in this sample (r_s = .831, $p<.001$). The effect size for this correlation is considered to be large and suggests that the correlation between IRB FTEs and number of studies should be considered by practitioners in developing their staffing model for IRB offices.

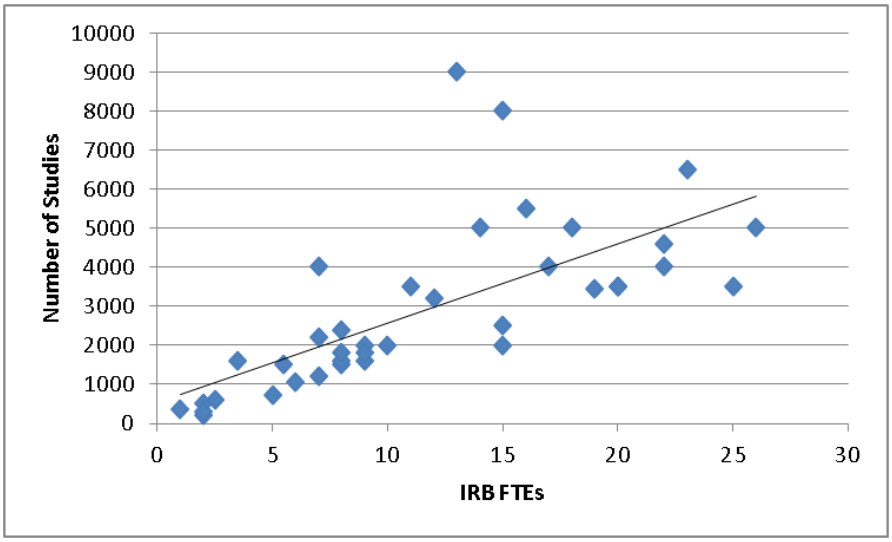

Figure 2. Number of IRB FTEs vs. Number of Annual Studies

Comparison of Number of Studies vs. IRB Computer Systems

Figure 3 depicts the difference in mean number of active studies for IRBs with and without an electronic system. The results of a Mann-Whitney U test (Mann-Whitney U = 89, p = 0.154) indicated no difference in the median number of studies for those who reported not having a computer system [1800 (425, 3750), *n*=9] and for those who reported having a computer system [2500 (1600, 4300), *n*=29].

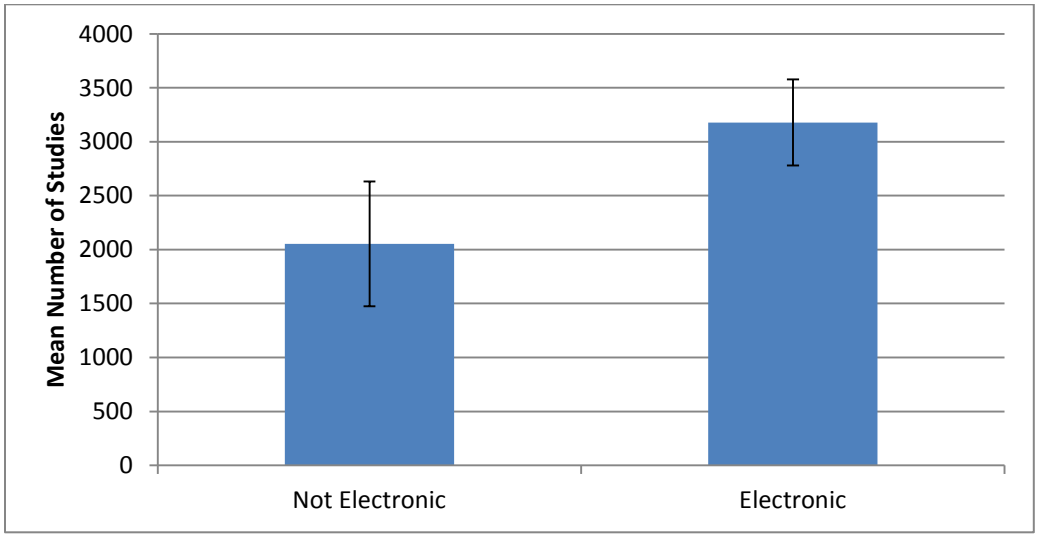

Figure 3. Mean Number of Studies for Offices with and without a Computer System

Comparison of Number of IRBs vs. IRB Computer Systems

Figure 4 depicts the difference in mean number of IRBs for institutions with and without an electronic system. The results of a Mann-Whitney U test (Mann-Whitney U = 102.5, p = 0.161) indicated no difference in the median number of IRBs for those who reported not having a computer system [3 (1, 4.5), *n*=9] and for those who reported having a computer system [4 (2, 4.5), *n*=29].

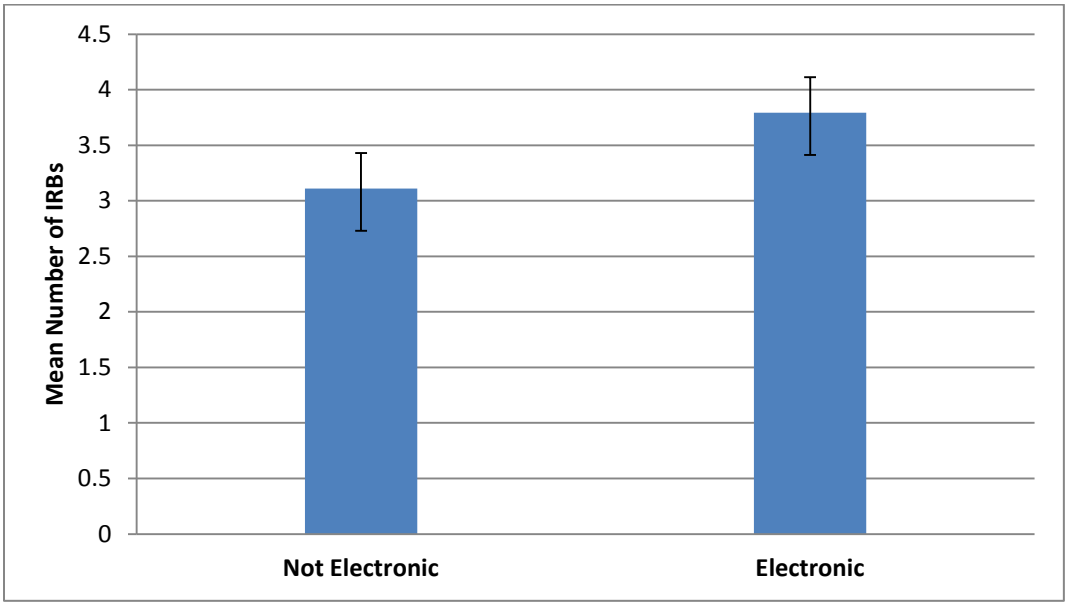

Figure 4. Mean Number of Studies for Offices with and without a Computer System

Comparison of IRBs Grouped by Number of Studies vs. IRB Computer Systems

The data were grouped into study categories defined by AAHRPP (see Table 3) (AAHRPP, 2013). A Mann-Whitney test was performed on the categorized data to determine the validity of the alternative hypothesis that an organization with a large number of studies is more likely to have a computer system. The Mann-Whitney U test (Mann-Whitney U = 77, p = 0.0275), determined that there is a statistically significant difference for the categorized data when comparing those IRBs with and without a computer system. Figure 5 graphically depicts the increase in the percentage of computerized IRBs as a function of the number of protocols processed per IRB.

Table 3
Number of Study Categories

Number of Studies	*N* (%)	% with Computer Systems
1–100	0 (0)	0
101–500	4 (10)	25
501–1,000	3 (8)	67
1,001–2,000	11 (29)	82
2,001–4,000	11 (29)	82
4,000+	9 (24)	89

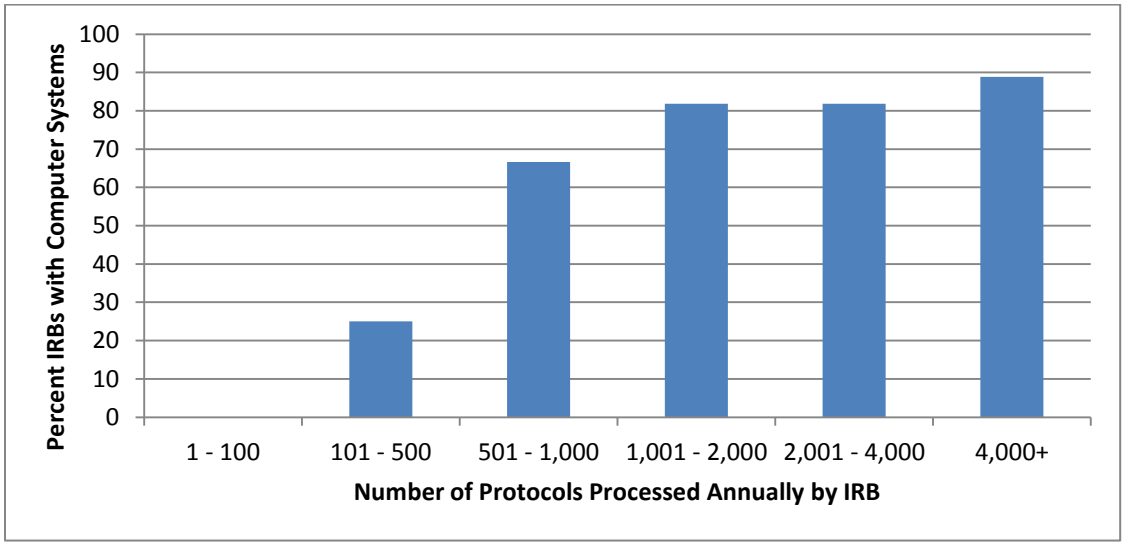

Figure 5. IRBs Categorized by Protocol Volume vs. the Percent with a Computer System

Comparison of Percent of IRBs with Computer Systems vs. IRBs with AAHRPP Accreditation

Figure 6 compares the percentage of IRBs with computer systems with those that have AAHRPP accreditation. The chi square analysis for the association between having a computer system (yes, no) and AAHRPP accreditation (true, false) indicated no significant association between having a computer system and AAHRPP accreditation ($\chi^2_{(1)} = 1.377$, $p<.241$).

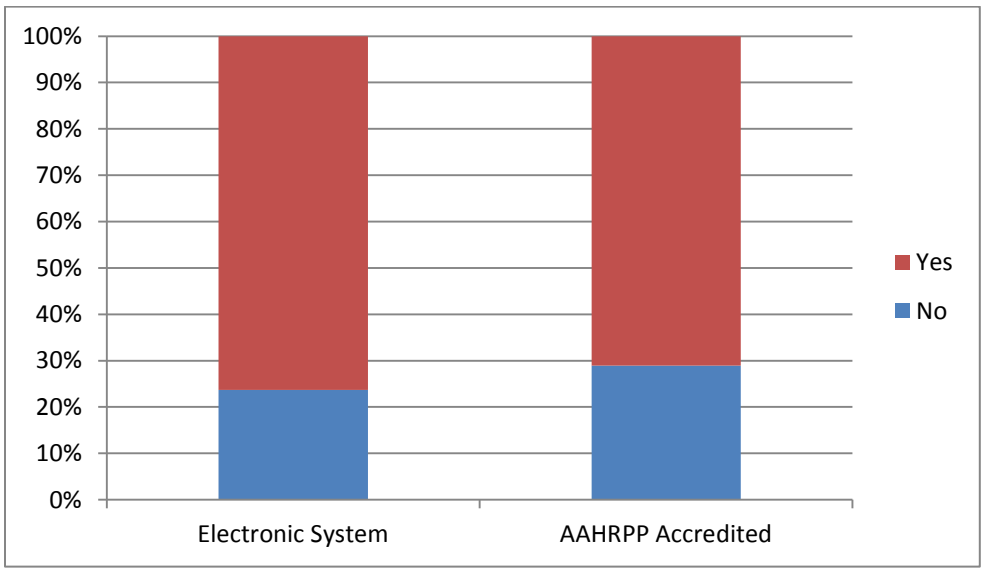

Figure 6. Percent of IRBs with Computer Systems and Percent of IRBs with AAHRPP Accreditation

Comparison of Application Processing Time vs. IRB Computer Systems

The data were also analyzed to see if the processing time for expedited or full board studies was impacted by the presence of a computer system. The difference in mean processing days for an expedited study (without a computer system, 23.8 ± 14.8, n=8; and with a computer system, 22.2 ± 13.4, n=29) was examined. The study data indicated that a computer system does not impact the mean days for an expedited study (independent $t_{35} = 0.289$, $p = 0.775$). The difference in mean processing days for a full board study (without a computer system, 43.56 ± 24.9, n=9, and with a computer system, 39.2 ± 18.8, n=29) was also examined. The study data similarly indicated that a computer system does not affect the mean days for a full board study (independent $t_{36} = 0.566$, $p = 0.575$).

DISCUSSION

The null hypothesis for the study is that there is no difference in the mean number of IRB FTEs for organizations with or without a computer system. The results of the study indicate that the presence of a computer system has no effect on the number of IRB FTE staff members. However, the statistical analysis of the effect of number of studies on IRB FTE count revealed that organizations with more studies have a higher FTE count (see Figure 3).

This study also examined whether the number of studies influenced an organization's decision to have a computer system. Figure 4 seems to indicate that organizations with more studies are more likely to have a computer system. Unfortunately, the statistical analysis did not support that hypothesis. However, it seemed that the large variation in number of studies [median = 2100 (1275, 4000), n=38] and the small sample size caused an issue with this statistical analysis. In order to smooth the variations in the data, the data were put into categories defined by AAHRPP (AAHRPP, 2013). A statistical analysis of these categorized data revealed that the number of studies processed by an IRB was an indicator of whether or not an organization used an IRB computer system. Figure 5 graphically depicts this result. An IRB that processes more studies annually is more likely to have an IRB computer system.

The study results were limited by several factors. Because the survey sample included only IRBs that belong to the University Health System Consortium, the association of the IRB with a UHC hospital may influence the ability of those IRBs to adopt computer systems for processing protocols. Additionally, due to the small sample size from a single membership group, the results may not be indicative of larger IRB office populations.

Therefore, future studies of the impact of computer systems on IRB staffing and efficiency should include a larger, more

diverse population of IRB offices. Also, the study should collect more detailed information regarding functions required of the computer system used by a particular institution. For instance, is the computer system used only to collect the protocol information or does it also support the workflow for processing review and approval of the protocol? This distinction would indicate the level of automation for the IRB office.

CONCLUSION

This study concluded that the number of staff in an IRB office is a function of the number of protocols that it processes. Also, the study found that IRB offices with more protocols are more likely to have a computer system. Further study is needed to determine if the results of this study are applicable to the larger population of IRB offices. Also, a future study should explore the impact of various computer system functions (e.g., collection of protocol information, automated workflows, virtual meetings) on IRB office staffing levels or protocol processing times.

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