

Determining the Costs of Institutional Review Boards

Considerable concern has been raised about the state of the system designed to protect human subjects participating in research.¹ Prominent among these concerns is that Institutional Review Boards (IRBs) have insufficient resources to oversee research portfolios that are growing in volume and complexity. However, the need for data quantifying the resource use and costs of ethics oversight are critical.²

Only limited data have been published regarding the actual costs of IRBs. In 1979, Brown and colleagues reported on the costs of operating a single IRB.³ More recently, Wagner and colleagues reported on the cost of IRB review within the Department of Veterans Affairs.⁴ While these reports provide important information, the former is arguably too old to be informative due to the radical changes in the research enterprise over the intervening time period, and the latter are restricted to the unique setting of the VA system.

There are three potential methods to ascertain the cost of IRBs. One method would involve prospective data collection of actual expenditures and activities. This method would produce the most reliable estimates concerning cost, but such data would be relatively expensive and burdensome to collect. Another method would be to obtain the actual costs of running an IRB from institutions. We found, however, that most academic institutions do not have a good idea of what their costs are, in part because many of these costs are indirect and therefore more difficult to track. Difficulty in accurately assessing IRB costs in institutions is not surprising. It is similar to the situation of many hospitals, which were unaware of the real costs of their operations until reimbursement changes in the late 1980s prompted them to use more explicit methods of cost accounting.⁵ Here we describe a third method that uses a retrospective assessment of resource use by IRBs to estimate costs. We have

used this method to estimate differences in costs of IRBs across institutions and among various types of research protocols.⁶ A similar method has been used to approximate overall health care costs,⁷ as well as costs for specific diseases and treatments,⁸ though little validation work has been done on any cost assessment methodologies.

Therefore we have two main objectives in this paper. First, we describe a methodology for estimating the cost of operating IRBs which relies primarily upon collecting resource utilization data through a survey. Second, we assess the accuracy and validity of the survey findings by conducting site visits with a sub-sample of institutions to collect information directly from institutional records for calculating IRB costs. As the second methodology is substantially more labor intensive, validation of the survey methodology would give institutions a less burdensome means to estimate costs.

Survey

■ **Survey Design.** A survey instrument was developed to capture the costs of IRB oversight. Based on the results of a pilot survey with three institutions, it became clear that we could not expect to achieve good data by simply asking each institution to report costs for the various resources used (e.g., salaries, space, etc.). Therefore we asked about units of resources used and the educational background and duties of personnel, and assigned monetary values to them. The final survey included items concerning IRB oversight for a specified one-year period as follows:

- The number of new full, new expedited, and continuing protocols reviewed.
- IRB personnel information including
 - education, experience, and job title of staff members;
 - the composition of boards including the number of chairs, vice-chairs, as well as their level of education; and
 - an estimate of the number of hours spent by

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board and staff members on human subjects protection activities.

- The amount of equipment and space used by the IRB.
- The monetary cost of travel and supplies for the IRB.
- The number of hours of outside services including telecommunications and technical support, legal or clerical services.
- Whether the IRB outsourced any of their review activities.

■ **Data Collection.** A list of U.S. medical schools (n=123) was obtained from the Association of American Medical Colleges (AAMC). Two Puerto Rican institutions were excluded. We defined the IRB at the institutional level; multiple panels within an institution were considered part of a single IRB. Recruitment letters were sent to each IRB administrator, and survey interviews were scheduled with the IRB manager or director. Participating institutions received a workbook, consent form, and study fact sheet. Respondents were encouraged to use the workbooks to collect relevant information from others on their board or staff.

Telephone survey interviews were administered primarily by Research Triangle Institute (RTI) using scripts developed collaboratively between RTI and the Consortium to Examine Clinical Research Ethics (CECRE). Ultimately, 69 (57%) of the eligible institutions participated in the survey concerning their 2002 IRB costs. Six respondents failed to complete significant portions of the survey; after repeated attempts to gather these data these institutions were excluded from subsequent analyses.

■ **Assignment of Monetary Values.** For all resource use except travel and supplies, for which we collected monetary values from the institutions themselves, we assigned a "price" to each reported unit of resource used. To determine the monetary value of IRB staff time, each staff person was assigned one of nine job codes: Academic Director/Coordinator; Non-Academic Director/Coordinator; Deputy Director/Coordinator; IRB Specialist; Technical Writer; Secretary; Education Coordinator; IT Specialist; and Student Help. Information from an organization that collects salary data was used to calculate the wage rates for each job code.⁹ The total number of hours worked by each type of staff member per week, estimated by the respondent, was multiplied by the wage rate, and by the number of weeks per year to create a one year estimate.

The choice of using a national wage or salary level, which is assigned to all IRB staff, regardless of the location of the institution, was deliberate. An alternative would be to collect regional salary levels and apply them only to the institution in that area. Regional cost differences can be large for labor rates and in real estate costs. However, one goal of the larger CECRE Cost Study project was to allow for comparisons among IRBs with different characteristics (e.g., geographic location and protocol volumes) so standardized values were necessary.¹⁰

Twenty-five job salary codes were created to describe the estimated salary levels for each board member, based on information obtained from the AAMC Faculty Salary Report for 2001-2002,¹¹ the U.S. Department of Labor's Bureau of Labor Statistics, Occupational Employment Statistics,¹² and the National Center for Education Statistics.¹³ These data were used in computing the personnel cost per year for board members (the product of 1: the respondent's estimate of monthly time spent by each type of board member; 2: the number of members in each position; 3: estimated salary; and 4: 12 months).

Equipment costs were estimated from prices listed by three national equipment suppliers. The square footage of space used was multiplied against an average national office space cost of \$25.20 per square foot in 2002.¹⁴ Costs of services provided by individuals or groups outside the IRB structure (outside services) were also gathered, including: technical support/information technology; telecommunications; legal services; outside clerical services; repairs and maintenance; and any other outside services. National estimates of hourly rates for these services were then applied.

■ **Estimating Costs.** There were a few cases in which institutions provided such extremely high costs for travel and supplies that we felt there must have been an error in their estimation. In these cases a maximum value was allowed. For travel the maximum was \$50,000 (utilizing the highest cost reported among those in the normal distribution) with three sites being restricted to this level, and a maximum of \$15,000 for supplies with four sites being so restricted. In addition, one site reported buying approximately 20 computers and 20 printers in the index year, which resulted in very high equipment costs which we restricted to \$19,500. For equipment and supplies we used three times the median cost for a maximum value.

The total cost per year for each institution was calculated as the sum of the cost of board time, staff time,

travel, equipment, supplies, space, and outside services. While many IRBs do not directly pay board members' salaries this opportunity cost is usually borne by the individuals or the larger institution and thus represents a real cost of the IRB. Similarly the cost of office space may not be directly paid by the IRB, but can be considered an opportunity cost for the institution. Cost per protocol was calculated by dividing total cost by the number of protocols reviewed. Costs per protocol were not computed for four sites due to a lack of information about protocol types reviewed; therefore, 59 sites are included in these analyses.

A sensitivity analysis was performed to determine how the output of the model (total cost) would vary if different assumptions were made about each of the factors in the model, in this case the major elements driving costs. Thus, for each of our standard prices, we applied estimates that were approximately 25% higher and lower, sequentially, and recalculated results.

Site Visits

On-site validation visits were conducted at 10 respondent institutions that were geographically diverse, public and private. These 10 sites were determined to have costs that were not statistically different from the 53 remaining sites. The site visits were performed according to a protocol developed with a certified public accountant experienced in estimating the costs of oversight of research with human participants. The site visitors conducted in-depth interviews with IRB directors and senior staff at each institution. In addition to the interviews, the visits included a review of IRB meeting minutes and where appropriate, budget and financial documents. Each site visit was supervised by either the accountant or one of the investigators with an advanced degree in business administration. All data were then analyzed and summarized by the accountant.

■ **Staff and Board Costs.** Staff costs were calculated by reviewing office roster and salary data for 2002. Additionally, we obtained each institution's fringe benefit rate for 2002 and applied these rates to all staff members receiving benefits. Board time costs were calculated by reviewing the panel rosters. We collected data concerning stipends or other forms of financial support/compensation to board members as well as information on how many hours per month each type of board member spent on IRB-related activities and an average annual salary for each type of board member. We then calculated a percent effort based on a total of

Table 1. Comparison of Respondent Institutions to All U.S. AAMC Institutions

Characteristics	Respondents (n=69)	AAMC (n=121)
Region ^a		
Central	20 (29%)	31 (26%)
North	20 (29%)	35 (29%)
South	20 (29%)	39 (32%)
West	9 (13%)	16 (13%)
Ownership/Control ^a		
Public	37 (54%)	73 (60%)
Private	32 (46%)	48 (40%)
	median (range)	median (range)
# faculty (incl. Instructors) ^a	942 (118-5,917)	864 (118-5,917)
# students (medical only) ^a	562 (170-1,124)	539 (161-1,278)
NIH funding rank ^b	56 (1-115)	61 (1-121)

^a American Association of Medical Colleges (AAMC), Medical School Profile System and Organizational Characteristics Database, 2002 (www.aamc.org, accessed 7/17/04).

^b NIH Awards to Medical Schools by Rank, Fiscal Year 2002, Source: Pub92021 Program med_rank_030925_rfm.

173 work hours per month (e.g., 10 hours on IRB activity/month would be roughly 5% effort). We applied this percent effort to the average salary and then multiplied by the number of board members in that category. The sums for each group were then aggregated to arrive at total board costs for each institution.

■ **Office Space Costs.** We calculated the square footage of IRB office space from either floor plans or the institution's facilities management office. We then applied the same national estimate of cost per square foot of office space (\$25.20) for 2002 as was used in the survey estimates to produce an estimated office space cost.

■ **Outside Services and Other Costs.** We asked each institution about support services received, including: technical support/information technology; telecommunications; legal services; outside clerical services; repairs and maintenance; and any other service. We asked whether these services were provided by the institution at no direct charge or provided by the institution or an outside entity for fees. For all of the above categories, we asked how much was directly spent by the IRB for these services in the index year. In addition we asked if institutions had cost items that they were unable to categorize; only one institution reported these and it was determined that they could be counted as supply or equipment costs. The cost of outsourcing protocols was

Table 2. Median Total Costs of IRB Activities by Method

	Overall Survey, N=63		Survey, N=10*		Site Visit Cost Validation, N=10		p-value†
	Median	Range	Median	Range	Median	Range	
Staff salary	463,107	85,246-3,103,397	511,069	305,651-1,001,899	579,290	275,200-848,700	N.S.
Board salary‡	219,349	23,303-2,476,471	231,402	48,382-458,204	364,568	131,600-921,220	N.S.
Space§	37,800	504-226,800	37,800	18,043-105,840	50,400	27,720-113,400	N.S.
Outside Services	13,347	0-275,469	15,878	5,561-118,163	11,500	3,251-73,544	N.S.
Equipment & Supplies	7,073	0-33,420	9,902	0-19,500	15,220	4,000-45,090	N.S.
Travel	3,500	0-50,000	4,250	0-30,000	11,280	6,000-30,000	N.S.
Other costs	NA		NA		0	0-36,140	
TOTAL	781,224	171,014-4,705,333	951,135	443,822-1,359,596	1,025,102	482,695-1,946,320	N.S.

*These are the same 10 sites at which site visits were subsequently conducted.

†Two-tailed paired t-test comparing Survey and Cost Validation results of 10 sites, with a Bonferroni correction for multiple comparisons significance is achieved at 0.008. N.S. indicates results not significantly different between methods.

‡Salary costs include a fringe rate of 26.05%.

§Space costs were calculated as square footage multiplied by \$25.20. If a square footage response was not given it was estimated by multiplying number of staff by an average square foot per staff member calculated from those sites that did respond.

Totals do not reflect the sum of the columns as they are median figures.

included in the outside services category, but in the data collection year there were very few protocols outsourced at these 10 institutions.

Data Analysis

Differences in total costs by category, ownership type, region and volume were compared with the Wilcoxon Rank Sum test and paired t-test. All analyses were two-sided. Results were considered to be statistically significant if they achieved a p-value of less than 0.05/number of comparisons (i.e., Bonferroni correction). For Table 2 this is a p-value of $0.05/6 = 0.008$. Data analysis was performed with UNIX SAS version 8.1.

Table 1 describes the respondent institutions compared to all U.S. medical schools using data from the AAMC and funding data from the National Institutes of Health. Overall, there are strong similarities among respondent and nonrespondent institutions.

Table 2 shows the median and range of costs to an IRB by each of our categories of cost as found by the survey for all institutions, by the survey for the 10 institutions that had site visits, and by the cost validation study (CVS). The median cost of running an IRB among the 63 sites surveyed was \$781,224 with a range from \$171,014 to \$4,705,333.¹⁵ Among the 10 sites that were also included in the site visits the median total cost was \$951,135 (range \$443,822 to \$1,359,596) and the cost found using the site visit method was \$1,025,102 (range \$482,695 to \$1,946,320). These costs were not

significantly statistically different. The largest drivers of the total cost are staff and board costs, which the 10 site survey estimated at an average of \$511,069 and \$231,402 respectively. The site visit method found average staff and board costs of \$579,290 and \$364,568 respectively. The higher staff and board costs found by the site visit method did not meet the criteria for a statistical significance from the survey estimate. The difference between the CVS and survey board cost estimates was more than 25% (of the CVS estimate) at eight of the sites, and in only one case were the staff cost estimate differences this large. There were not statistically significant differences in the estimates using both methods for space, equipment/supplies, and travel. At only three institutions did the site visit find exactly the same number of full-time-equivalent (FTE) staff members as the survey; another three differed by less than one FTE. The survey underreported staff at two sites by 1.5 and 2 FTEs, and overreported at two sites by 2 and 4 FTEs.

When gathering costs in the site visits, both salary and fringe benefits were captured. The fringe benefits accounted for between 17% and 33% of total staff costs, with an average of 25%. Board costs included both direct compensation and stipends and a separate cost for miscellaneous food, parking and other costs.

The total costs found by both methods for each of the validation sites are given in Table 3. Here a direct comparison can be made of the two methods. If we assume that the site visit is the best available estimate of cost (i.e., the gold standard) then the survey underestimates

Table 3. Comparison of Survey and Cost Validation Results

#	Ownership	Region	Protocol Volume	Total Cost (\$)			Error %*
				CVS	Survey	Difference	
1	Public	South	low	942,856	613,964	-328,892	-35%
2	Private	Midwest	high	1,946,320	1,359,596	-586,724	-30%
3	Private	Midwest	low	531,220	461,295	-69,925	-13%
4	Public	West	high	1,476,600	1,319,855	-156,745	-11%
5	Private	Northeast	high	1,495,890	1,347,425	-148,465	-10%
6	Public	South	low	482,695	443,822	-38,873	-8%
7	Private	Northeast	mid	1,211,306	1,121,047	-90,259	-7%
8	Private	South	mid	751,571	781,224	29,653	4%
9	Public	Midwest	high	1,107,347	1,212,592	105,245	10%
10	Private	Northeast	mid	521,166	629,284	108,118	21%

* Error = $(x_i - y_i) / y_i$ where x_i is the survey cost at institution i and y_i is the CVS cost at institution i .

the total cost of IRB activities at seven institutions. Dividing the site validation cost by the cost difference gives the percent error. Among the seven underestimated sites the percent error ranged from 7% to 35%. Three sites were over-estimated and the percent error ranged from 4% to 21%. The difference in the total cost as computed by the two methods was less than \$100,000 in four cases, and over \$200,000 in two cases.

In order to address the concern that a systematic bias might produce consistent mis-estimates of cost, we compared survey and site validation results by the type of institution (Table 4). The absolute mean error is the sum of the absolute values of the cost differences among all sites of one type (e.g., Midwestern schools) between the two methods, divided by the total cost found by the CVS, divided by the number of sites. Among the six private medical centers the absolute mean error was 14.2%, while among the four public institutions it was 15.8%. When compared by the volume of protocols handled during the year the absolute mean cost differences were highest among the low volume sites (18.7% at institutions reviewing fewer than 350 protocols) than high volume (15.0% at institutions reviewing more than 700 protocols) or medium volume (10.7% at institutions reviewing 350-700 protocols). As expected, total costs increased substantially with protocol volume (details on the cost variations by volume, and cost per protocol have been published elsewhere).¹⁶ Paired t-tests revealed no statistically significant difference between the cost estimates measured by ownership, region or volume of protocols at each institution.

A sensitivity analysis was performed to study how much the estimation of total cost found by the survey would vary if different assumptions were made about the major drivers of IRB cost. If the lowest reasonable assumptions are made for board and staff salaries, outside services and office space costs, then the lowest estimate of total cost is created, and an upper estimate is created if the highest cost assumptions are used. This creates an estimate of the range of total costs, within which it is likely that the actual value lies. We then compared the results found by the CVS to the ranges computed in the sensitivity analysis. In all but three of the sites the staff salaries found by the CVS fell within the range of the sensitivity analysis. In only one site did the board costs found by the validation study fall within these limits. The total IRB cost found by the validation study fell within the boundaries of the sensitivity analysis of the survey for three sites.

Discussion

Overall our survey method of estimating the costs of IRBs produces results that are not significantly different from a site visit in estimating the costs of running an IRB. Values for various components of cost differ, but not significantly. A limitation of both methods is that they are retrospective, and may inaccurately reflect real costs depending on the level of detailed records each IRB has available.

The major drivers of cost, as previously reported,¹⁷ were staff and board costs. The survey of 10 sites produced a statistically insignificant underestimate of

Table 4. Comparison of Cost Differences between Survey and CVS by Institution Type*

Institution Characteristic	N	Total Cost (Median)		Absolute Mean Error%†	Sites Overestimated (N)‡	
		CVS	Survey			
Ownership	Private	6	981,439	951,135	14.2	2
	Public	4	1,025,102	913,279	15.8	1
Region	Midwest	3	1,107,347	1,212,592	17.6	1
	Northeast	3	1,211,306	1,121,047	12.7	1
	South	3	751,571	613,965	15.6	1
	West	1	1,476,600	1,319,855	10.6	0
Volume	Low	3	531,220	461,296	18.7	0
	Mid	3	751,571	781,224	10.7	2
	High	4	1,486,245	1,333,639	15.0	1

* No statistically significant differences were found between CVS and survey estimates by each type of institution (i.e., private, public, Midwest, etc.).

† Mean Error = $\frac{\sum_{i=1}^N |x_i - y_i|}{N}$ where x_i is the survey cost at institution i and y_i is the CVS cost at institution i , summed over all institutions of type j .

‡ The number of sites in each group in which the survey estimate was larger than the CVS estimate.

\$68,000 in staff costs compared to the site visit. Differences in staff costs between the survey and site visits could be due to accuracy of reporting and local salary differences. Seven sites reported different numbers of staff at the site visit as compared to their survey responses. Discrepancies may have been the result of reporting errors on the initial survey since the review of staff rosters during site visits is likely to be more reliable. Additionally, in the survey we used national average wage rates to calculate the staff costs. It may be that the university's salaries for administrative and staff positions are lower than in other sectors.

Overall, the survey produced a large, but still statistically insignificant underestimate of board costs of approximately \$133,000. The site visits sought to capture stipend and other meeting costs (i.e., food, parking) that the survey did not collect. However, these accounted for on average only 2% of the board costs. In general, few board members are directly compensated by the IRB for their time. For this reason, tracking the total number of hours spent by IRB members may not be of high priority for IRB staff.

The survey overestimated office space costs by \$12,600 per year. In both methods it appears that respondents' estimates of square footage were less than those reported by facilities offices or found on floor plans. Outside services were overestimated by about \$4,400 in the survey. Equipment, supplies, and travel are minor amounts in the IRB budget and were generally

underestimated by the survey method. In general we found that changes made in midyear (to staff, services, etc.), were more likely to be mentioned by the respondent at the site visit than in the survey.

In general this study has captured the labor intensive nature of IRB activities as reflected by the high proportion of administrative and board member costs. The opportunity costs of IRBs have historically not been measured by many institutions. Our study provides insight into the significant and valuable time that board members dedicate to the IRB. It may assist decision-makers in evaluating the potential need for additional resources to handle growing demand and assessing how to provide sufficient capital to support their IRBs in the future. Some institutions have chosen to impose fees on sponsors of clinical trials in order to cover IRB and other costs, and a greater understanding of these costs might be helpful in determining if these fees are reasonable.

Our study has several limitations. The costs incurred in sending professionals to verify data at each institution limited us to 10 site visits. While our data indicate the survey method to be reasonably accurate, it is possible that if more sites were visited larger discrepancies may have been found. In addition, the survey method relies on self-report of staff and board time, space usage, travel, etc., and any component may be misestimated by the respondent. For some items respondents did not know the answer or did not answer, and in these instances we

either imputed data or removed the observation. Data from the site visit are also limited, as even with professional accounting methods it is difficult to estimate costs from some IRB records which are often not kept in the same manner as business records. The data are also limited by the choice to only include IRBs at U.S. medical schools. Nonetheless, the survey method is intended to be flexible enough to apply to institutional IRBs regardless of size. However, there may be variations in non-academic, independent and non-U.S. settings which would require modification of the method to adequately capture all costs.

Despite the tendency to underestimate using the survey method, considering the amount of resources and expertise needed to calculate costs using site visits, institutions and policy makers interested in mapping the costs of IRB oversight should feel relatively comfortable using the methods employed in the survey to establish reasonable estimates. In the future, it would be interesting to examine the reasons for cost differences across institutions as well as the differences in how they are structured and function. A detailed look at how these IRBs are run, together with their costs, may be able to produce recommendations to improve cost efficiency without sacrificing quality.

Deliberations about the appropriate compensation of institutions for IRB oversight should incorporate its true costs. Our methodology can be used by any specific institution to estimate the costs incurred by its own IRB. Although it is unclear whether the current resource use by an IRB is the appropriate amount for optimal IRB performance, an estimate of the current costs will provide information that will be useful in preparing budgets and working to ensure adequate resources. Future research is needed to understand how these investments relate to the quality of IRB review and oversight and whether these investments are sufficient to meet the ethical goal of protecting human research participants.

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The study was approved by the Duke University Medical Center IRB; the data analysis phase was deemed exempt by the IRB at the Johns Hopkins Medical Institution.

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