APPENDIX ON ESTIMATING THE COSTS OF INSTITUTIONAL REVIEW BOARDS AND TESTING FOR ECONOMIES OF SCALE

The first section of this appendix describes how we estimated costs, and the second section discusses some analytical details.

Estimating Institutional Review Board Cost

Unlike hospitals, there is not an administrative dataset that contains the costs of operating IRBs. In fact, many IRB administrators do not have budgets. Therefore, our first task involved using microcost methods to estimate costs for our sample of VA and VA-affiliated IRBs.

The cost of operating the IRB was estimated as the sum of 1) personnel costs, 2) space costs, 3) supplies, and 4) education and training. To calculate the personnel costs, we multiplied personnel time, using the full-time equivalents (FTE), by salary, in which each salary was a function of education, tenure, and job category.

In line with recommendations for the economic evaluation of health programs,[36] this study adopted the societal perspective, which treats all costs equally irrespective of who bears them. For example, if the IRB chair donates his or her time to the IRB, these costs are included even though they might not in the IRB's budget. The IRB costs also include committee members. We did not survey committee members because it was not feasible, so our cost estimates excludes any time they spent outside of meetings.

Personnel

VA pays employees according to Federal pay scales, with locality cost-of-living adjustments. Academic affiliates have their own pay scales, which probably reflect geographic cost-of-living differences. To estimate national costs, personnel time for the IRB administrator and staff was valued using 2001 national wage rates. We combined information on each person's education and tenure to differentiate salary levels (Table 3).

For salary estimates, we used the 2001 national federal pay scales (www.opm.gov). We divided the different IRB personnel into 5 categories. We then assigned the grade and step level for the low, mid, and high salary ranges for each position (see Table 4).

Once the person's base salary was estimated, we included a benefit rate of 28%. The total was then multiplied by the person's FTE. For administrators, we collected the exact FTE. For other personnel, the administrator was asked whether they were full-time or part-time. Staff members working part-time (38%) or having missing FTE data (<1%) were coded as 0.5 FTE.

We estimated the chairs' FTE based on the amount of time they reported spending on IRB activities in a usual month. We also collected information on whether the chair was paid from the IRB budget or was given release time from clinical duties. We estimated the chair's cost based on VA administrative data that indicated that the average chair's salary was $93,158 in 2001. In the sensitivity analysis, we varied this up to $161,200, which was the maximum reimbursement for an MD allowed by the National Institutes of Health in 2001. This information was used to determine the difference between the societal perspective and the typical IRB budget.

We included the committee members' time spent in meetings. Committee member salaries from VA administrative data averaged $82,517. The median time spent in committee meetings during the past year was 12, 26, and 53 hours for small, medium, and large IRBs, respectively. Thirty-two percent of administrators did not report the length of committee meetings, so we used the median to account for missing values. We did not directly survey committee members, and therefore did not include any time they spent outside of meetings.

Space

To calculate space costs, in the survey, we collected information on the type of office space: own office, shared office, own cubicle, and shared cubicle. We also asked about the presence of a copy room, conference room, and filing room, and whether the space was shared with another department. To estimate the average square footage per type of office (own, shared, cubicle, copy room, conference room, and filing room), we used information from a commercial real estate web site.[37] The 1 exception was that administrators self-reported the size of their office.

In our survey, 87% of the administrators had their own office, whereas 13% shared an office with another person. The average administrator office size was 13 feet × 15 feet (195 square feet). Table 5 shows the types of office space that the IRBs used, and whether they were shared with another department. The majority of IRBs had a dedicated meeting room (93%), 76% had a copy room, and 77% had a filing/storage room. The meeting room space was often shared with another department (82%), compared with the copy room (61%) and storage/filing rooms (42%).

The copy room and meeting room were assigned 150 and 180 square feet, respectively. The filing rooms for small, medium, and large IRBs were 100, 150, and 200 square feet, respectively.[37] IRBs that reported to share this space were assigned 50% of the space.

We multiplied the total square footage times the annual rental rate per square footage, taking into account the employee's FTE. Rental rate estimates were obtained from a real estate web site that tracks rental rates across the country.[38,39] The weighted national average for 2001 was $34.71 per square foot per annum, and we used this amount as the estimated rental rate.[37]

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TABLE 3. Estimating Salary Based on Education and Tenure

Tenure in Job	Education: High School	Assoc.	BA	MS	Doctoral Degree
<1 year	Low	Low	Low	Mid	High
1–2 years	Low	Low	Mid	Mid	High
3–5 years	Low	Low	Mid	High	High
6+ years	Low	Mid	Mid	High	High

Supplies

Fourteen IRB administrators provided expenditure information on supplies. Supply costs were variable, depending on IRB size (ie, volume). We divided the cost of office supplies and equipment as reported by the IRB administrators by the total number of actions processed by the IRB in the last year. From these data (n = 14), we calculated supplies costs at $17.90 for each action. This calculation assumes that supply costs are the same for large and small IRBs. This might not be true, because large-volume buyers often receive a better price. We tested this assumption in the sensitivity analysis.

With an estimated supply cost per action, we imputed supply costs for all IRBs. This was done by multiplying $17.90 by the number of actions at each IRB. This method assumes that supplies are a function of the number of actions processed. We then added the costs for personal computers for each person. For sites with more than 2 people, we also included the cost of a local area computer network. For each computer, we used a $1800 purchase price with a straight-line depreciation over 3 years and no salvage value. We estimated the costs of the local area network and its maintenance at $1000 per user per year.

The survey indicated that supplies are a relatively minor budget component compared with personnel costs.

TABLE 4. Salary Chart

Job Category	Grade and Step Level	Salary
Clerical/Administrative		
Low	GS7-step 1	$29,273
Mid	GS9-step 1	$35,808
High	GS11-step 3	$46,214
Database/Computer Analyst		
Low	GS9-step 1	$35,808
Mid	GS9-step 5	$40,580
High	GS11-step 3	$46,214
Compliance officer		
Low	GS11-step 1	$43,326
Mid	GS12-step 1	$51,927
High	GS13-step 1	$61,749
Coordinator		
Low	GS9-step 1	$35,808
Mid	GS9-step 5	$40,850
High	GS11-step 3	$46,214
Director		
Low	GS11-step 3	$46,214
Mid	GS12-step 3	$55,387
High	GS13-step 3	$65,867
Chair*		$93,158
Committee member†		$82,517

*Average from VA administrative data; varied in the sensitivity analysis to $161,200

†Average from VA administrative data

TABLE 5. IRB Space

	% of IRBs With This Room	Share Space With Another Department
Copy room	76%	61%
Meeting room	93%	82%
Storage/filing room	77%	42%

Education and Training

Thirteen IRB administrators provided expenditure data for employee education and training. To calculate training and education costs, we divided the cost of education and training as reported by IRB administrators by the total number of staff at the IRB in the last year. From these 13 sites, we calculated that training and education costs averaged $1155 for each staff member per year. We then used this cost estimate to calculate the training costs for all IRBs. This method assumes that providing education and training to staff is a function of the number of staff members. The survey indicated that supplies are a relatively minor budget component compared with personnel costs.

Other individuals and resources are required to operate an IRB. For example, Federal regulations require oversight activities by institutional officials. Also, some complex protocols require legal advice. We did not estimate these costs.

Data Reliability and Validity

Estimating IRB costs is highly dependent on the reliability and validity of the reported data. In particular, because IRBs perform a service, personnel are the primary cost. Therefore, we attempted to validate the personnel data using 2 approaches.

First, approximately 6 months after the survey, we sent all respondents the same questions on IRB staff and FTE. The

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TABLE 6. Estimated IRB Cost Function

	Cobb-Douglas Total Cost (logged)	Translog Total Cost (logged)
IRB size		
Number of actions	0.38 (9.05)†	0.46 (1.60)
Number of actions squared		−0.02‡ (0.27)
Protocol characteristics		
Share of full board new reviews	ref	ref
Share of full board continuing reviews	0.12 (0.29)	0.13 (0.30)
Share of full board amendments	−1.02 (1.27)	−1.11 (1.27)
Share of expedited new reviews	−0.8 (1.04)	−0.66 (0.69)
Share of expedited continuing review	2.36 (1.92)	2.45 (1.91)
Share of expedited amendments	−0.54 (0.78)	−0.58 (0.81)
Share of exempt	1.91 (1.69)	1.98 (1.70)
Share of AERs	−0.36 (1.19)	−0.34 (1.05)
IRB quality proxies		
IRB performance scale (natural log)	0.38 (1.05)	0.35 (0.90)
Administrator is certified	0.2 (1.19)	0.21 (1.21)
Percent of chair's salary paid in thousands	0.15 (0.84)	0.15 (0.83)
Constant	9.68 (31.20)†	9.49 (12.71)†
Observations	67	67
R^2	0.73	0.73

Absolute value of t statistics in parentheses
†significant at 1%
‡F test for lnq and lnq2 is 8789.90 ($P < 0.0001$)

questions referred to staffing in August 2001 to approximate the time they completed the first survey. Twenty-four participants responded. With this information, we calculated an intraclass correlation coefficient (ICC) to test reproducibility. For both staff and FTE, the ICC was above 0.95, suggesting a high degree of reproducibility among the responders.

Second, to assess the accuracy and validity of the staffing data, we asked administrators to provide data on their budgets if available. Ten administrators in our survey provided budget information on personnel costs. Although our estimates are based on national salary estimates and do not include geographic wage adjustments, we would expect our estimated personnel costs to be correlated with the reported personnel costs. The data show a correlation of 0.94 (n = 10) between the actual personnel budgets and the estimated personnel budgets.

None of the administrators surveyed had a separate budget for space or rental costs. Although interesting, this meant that we could not assess the validity of our estimated space costs.

Data Assumptions

This study rests on some key assumptions with regard to the data. First, the data were collected with a survey, so we had to assume that the participants were providing accurate and valid information. Test–retest information on personnel was highly significant (n = 24), and the estimated costs were highly correlated with budgets, when provided (n = 10). Nevertheless, future research should consider using site visits to evaluate the accuracy of surveys. Second, other individuals and resources such as institutional officials and legal advice are required to operate an IRB. We had no method by which to estimate these costs and therefore excluded them from our calculations. Third, in calculating the total costs, we relied on national benchmarks for square footage and national salary estimates.

Analysis of Economies of Scale

Economies of scale refers to the organization's level of production. We assessed this by evaluating the cost function. The cost function for IRBs can be written as

$$C = C(p,y,m,a) \quad (1)$$

where C represents total costs, p represents a vector of factor prices, y a vector of output, m a vector of protocol-related case-mix attributes, and a represents IRB quality.

One of the problems with equation 1 is the lack of factor prices in our data. The microcosting method we used is based on gathering units from the survey and matching them

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TABLE 7. Average Costs Regressed on IRB Size

		Alternative Models	
	Main Model Semi-log	**OLS**	**Semi-log‡**
Small IRB	2.94 (2.51–3.38)†	3327.32 (1767.81–4886.83)†	2.91 (2.51–3.31)†
Medium IRB	1.26 (0.90–1.62)†	764.66 (−532.45–2061.77)	1.07 (0.80–1.34)†
Large IRB		Reference group	
% of time dealing with initial reviews	1.2 (−0.17–2.56)	5383.82 (−2084.41–12,852.05)	0.23 (−0.53–0.98)
% of time dealing with continuing/annual reviews	1.26 (−0.98–3.49)	3793.88 (−4272.40–11,860.16)	1.81 (−0.23–3.85)
% of time dealing with amendments	−1.82 (−4.42–0.78)	−9045.59 (−18,057.57–−33.61)*	−0.26 (−2.34–1.83)
% of time dealing with adverse event reports	−0.82 (−4.18–2.55)	6047.59 (−5887.98–17,983.16)	−1.69 (−4.87–1.48)
Administrator certified	0.24 (−0.10–0.57)	204.29 (−592.38–1000.97)	0.16 (−0.16–0.49)
Percent understaffed	−0.21 (−0.40–−0.01)*	−458.06 (−1040.40–124.28)	−0.25 (−0.45–−0.04)*
Percent of chair's IRB effort paid by IRB	0.23 (−0.16–0.62)	−49.65 (−1240.19–1140.88)	0.45 (0.13–0.78)†
Human subject office performance (0–1 higher is better)	−0.79 (−1.90–0.31)	−3397.61 (−7476.84–681.63)	−0.33 (−1.28–0.62)
VA IRB	−0.17 (−0.49–0.15)	−343.64 (−1249.04–561.77)	−0.12 (−0.39–0.14)
Constant	5.28 (4.35–6.21)†	1901.37 (−1108.17–4910.92)	4.91 (4.10–5.72)†
Observations	67	67	65
R^2	0.85	0.52	0.87

Dependent variable is the natural logarithm of the average unit costs
Robust 95% confidence intervals in parentheses
*significant at 5%; †significant at 1% (two-tailed test)
‡Excludes 2 outliers identified with Cook distance

with national cost estimates. Therefore, the cost estimates are fixed and do not vary across the IRBs. The personnel and capital costs, the 2 biggest cost components, were calculated in this manner. We gathered some budget data in our survey, but many did not have budgets. Moreover, when the IRB administrators did provide budget information, none ever included the space cost. Most of the office space is provided by the parent organization.

Does lack of factor prices affect our ability to test for economies of scale? The lack of factor prices raises questions about the IRB's objective function and whether the IRB attempts to minimize costs. All of the IRBs in our survey receive funds through their parent organization. These funds are constrained through regulation or administration; so at some level, we believe that there is some attempt to minimize costs. Our inability to control for factor prices has 2 other implications. First, it could bias the estimated marginal cost for different-sized IRBs. For example, smaller IRBs could be in less expensive markets. Therefore, we estimated a production function in which output was the dependent variable and factor inputs were the independent variables. Second, we are not able to estimate a share equation and use seemingly unrelated regression to estimate simultaneously the share equation and the transcendental logarithmic (translog). The latter method is common when estimating translogs.

To estimate equation 1 with a translog cost function, we must assume that the cost function is twice differentiable and is approximated by a second-order Taylor series expansion. The translog has a flexible functional form and places no restrictions on the partial elasticities. Limits with our sample size required that we estimate a hybrid cost function in which the IRB quality and protocol case-mix were entered as shift parameters and not fully interacted with the other variables. The vector of case-mix attributes and quality estimates had zeros and these were not logged. We also estimated a Cobb-Douglas cost function. The results were very similar. We present the hybrid translog because it provided the most conservative cost estimates for small IRBs.

Table 6 shows the cost function. The first column is the Cobb-Douglas and the second column is the hybrid translog

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TABLE 8. Economies of Production: Number of Actions Regressed on Factor Inputs

	Coefficients (t-statistics)
Employees: full time equivalents (logged)	0.67 (2.83)†
Office space: square feet (logged)	0.29 (1.11)
Protocol characteristics	
Share of full board new reviews	Ref
Share of full board continuing reviews	−2.76 (2.21)*
Share of full board amendments	4.46 (1.95)
Share of expedited new reviews	−5.82 (1.03)
Share of expedited continuing reviews	3.75 (0.86)
Share of expedited amendments	1.82 (0.88)
Share of exempt	10.98 (1.93)
Share of AERs	2.03 (2.36)*
IRB performance scale (logged)	0.02 (0.02)
Administrator is certified	0.01 (0.02)
Percent of chair's salary paid in thousands	−0.72 (1.35)
Constant	3.69 (2.09)*
Observations	67
R^2	0.40

Absolute value of t statistics in parentheses
*significant at 5%; †significant at 1%

cost functions. In both cases, large economies of scale are evident by evaluating the coefficient on the number of actions. For every 1% increase in output, costs increase by less than 0.5%, indicating large economies of scale at the mean of the sample.

The Cobb-Douglas and translog are linear in logs. To assess whether there was a U-shaped average cost curve, we used the following semilog regression model:

$$\log(\text{average cost}) = \beta\text{IRB size} + \delta\text{quality} + \phi\text{protocol mix} + \varepsilon \quad (2)$$

We measured size as the number the cumulative number of full initial reviews, expedited initial reviews, exempt initial reviews, full continuing/annual reviews, expedited continuing/annual reviews, amendments under full board review, amendments under expedited review, and harms/adverse event reports reviewed by the IRB in the last year.

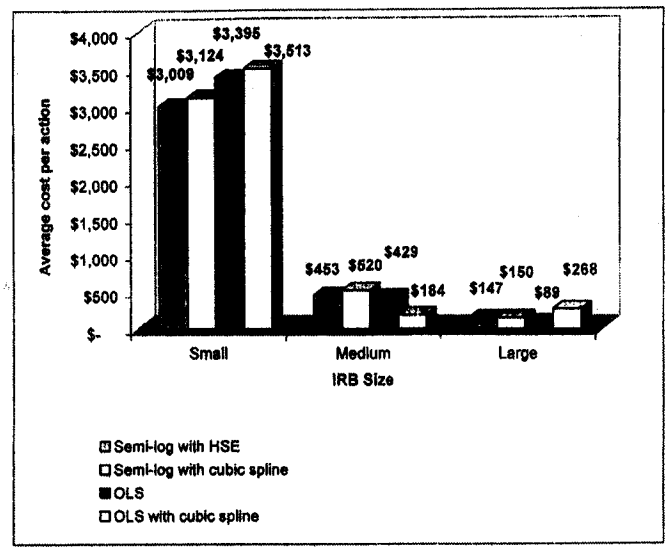

FIGURE 2. Estimated cost per action from analyses of the average cost curve. Note: Estimates from regression model, other held at mean. Costs are in 2001 dollars. HSE is heteroscedastic smearing estimator.

Approximately half of the distribution had fewer than 400 actions, but the distribution was skewed as a result of a few very large IRBs. For the regression analysis, we created 3 dummy variables for size: small, medium, and large. This allowed for a nonlinear relationship between size and average costs. The size designation was based on the 33% and 66% (tertiles) of the sample. The average number of actions in the small, medium, and large groups was 52 (range, 3–151), 431 (range, 152–826), and 2676 (range, 827–12899), respectively. As a less parametric and more flexible alternative, we fitted a cubic spline with 5 knots. This cubic spline was then included in the regression. Table 7 presents those results; we also show the results of the cubic spline in Figure 2.

Finally, we assessed economies of production. This involved regression the IRB's output on the factor inputs. The primary inputs were personnel (FTE) and space (square feet). This is shown in Table 8.

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