RECOMMENDATIONS FOR A NEW
ALLOCATION SYSTEM FOR 101 FUNDS

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HIGHLIGHTS

Objective
The VA Office of Research and Development (ORD) currently allocates approximately 7% of its budget to VA health care systems (VAHCS) to support their research administration activities. These allocations are known as "101 funds." This system is thought to be too inflexible and inadequate for research programs that are expanding and that are facing increasing regulatory demands, is overly dependent on a Medical Center's past performance, and is very difficult to update. We were asked by ORD to propose a new allocation method that addresses these limitations and is easy to calculate in terms of staff time and existing data sources.

Methodology
We conducted in-depth interviews with staff from eight VAHCS representing different facility sizes and geographic areas. We then surveyed all Administrative Officers (AOs), asking about staff, expenditures, and revenues. We used these findings to investigate the underlying needs of research administration at VAHCS, and through an iterative process, developed three alternative allocation models to meet these needs. To compare the three models, we simulated their effects on VA health care systems.

Summary of Proposed Models
The three proposed allocation models provide research offices with funds for core personnel, although they use slightly different formulae in the calculation. All three models use the health care system's size, as determined by the number of VA funded projects, to calculate the core personnel. Funds for additional personnel are provided based on the health care system's volume of protocols undergoing review by the oversight committees, such as Research Safety, Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC). Additional funds are provided for supplies and education. Finally, to meet each health care system's unique needs, they will receive flexible funds calculated at 3% of VA-funded research conducted at the health care system.

Financial Impact of Recommended Model
Of the three models, we recommend the Continuous Model, in which every VAHCS that conducts research would receive 2 FTE and an additional 0.12 FTE per VA-funded project. The approximate financial impact of the recommended model is as follows.
- Approximately 7% of ORD's budget is spent on research administration support. The new models would increase that amount to approximately 9.5% (a 35% increase).
- Total 101 funds going to small sites would increase approximately 134%.
- Total 101 funds going to medium sites would increase approximately 30%.
- Total 101 funds going to large sites would increase approximately 30%.
- In addition to core support for personnel, supplies and education, each site will receive "flexible funds." These are calculated at 3% of the VA funded research allocations and are to be distributed concurrently with the research allocation. Based on FY02 estimates, the average small, medium, and large sites would receive approximately $13,000, $86,000 and $247,000, respectively, per year in flexible funds.

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LIST OF TERMS

ACOS/R	Associate Chief of Staff for Research
AO	Administrative Officer
CO	Central Office
DHHS	Department of Health and Human Services
FTE	Full time equivalent
FTESIM	Simulated full time equivalent, based on the new allocation methods
FWA	Federalwide Assurance
HSR&D	Health Services Research and Development
HIPAA	Health Insurance and Portability Accountability Act
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
IRMS	Information Resources Management Service
ITA	Initial Target Allowance
NIH	National Institutes of Health
ORD	Office of Research and Development
R&D	Research and Development Committee
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VAHCS	VA Health Care System
VERA	Veterans Equitable Resource Allocation

RECOMMENDED ALLOCATION MODEL: THE CONTINOUS MODEL

We believe the qualitative and quantitative data we collected support the Continuous Model for allocating 101 funds. The allocation model is relatively easy to implement. This model starts by calculating the full-time equivalent (FTE) staff members for the research office. FTE then gets translated into a dollar amount. Therefore, although we discuss FTE in detail, ORD will still be allocating dollars to the research offices.

The **first step** in the allocation model involves calculating the number of FTE. We labeled this FTESIM for simulated FTE. To translate FTESIM into dollars, we recommend using the average salary cost (i.e., grade and step) in small, medium and large VAHCS. Employee benefits will be included based on national standards from the Office of Personnel Management, and these are approximately 28%. The total FTE allocation will receive the market area cost of living adjustment.

FTESIM is based on fiscal data from the prior year, with a mid-year correction. The FTESIM calculation reflects two factors: 1) the volume of research projects, and 2) the volume of work processed by committee support staff. Each of these factors is discussed in detail below.

1) Personnel based on number of VA-funded projects

- Every site will receive 2 FTESIM to cover fiscal services, basic committee support, purchasing, administrative assistance/clerical, staff education, regulatory compliance, and investigator education.
- For every VA-funded research project that the research office administers, the research office will receive 0.12 additional FTESIM.

2) Personnel based on the volume of committee effort

- FTESIM will be allocated to support the research safety, biohazard, Institutional Review Board (IRB), and Institutional Animal Care and Use Committee (IACUC) subcommittees, if they are directly run by the VA facility. The FTESIM will be apportioned in relation to the number of actions processed per fiscal year. Actions are defined as initial reviews, continuing reviews, and amendments.
    - For the IRB, sites will receive
        - No additional FTESIM if the affiliate handles the IRB
        - No additional FTESIM if the number of IRB actions is fewer than 50.
        - 1 FTESIM for every 200 IRB actions between 50 and 450
        - 1 FTESIM for every 250 IRB actions over 450
    - For the IACUC, sites will receive
        - No additional FTESIM if the affiliate handles the IACUC
        - No additional FTESIM if the number of IACUC actions (initial reviews, continuing reviews, and amendments) is fewer than 50.
        - 1 FTESIM for every 200 IACUC actions between 50 and 450
        - 1 FTESIM for every 250 IACUC actions over 450
    - Research safety and biohazards
        - No additional FTESIM if the cumulative number of actions (initial reviews, continuing reviews, and amendments) is fewer than 50.

- 1 FTESIM for every 200 actions between 50 and 450
- 1 FTESIM for every 250 actions over 450

The **second step** in the allocation model involves estimating the cost of supplies and training and education. Supply costs are based on workload in the prior year, while staff education and training costs are based on FTESIM. Both are described below.

Supplies
- Each year, the research office will receive $50 for each IRB action, IACUC action, research safety and biohazard action.
- The research office will receive $500 per fiscal year for every VA funded project that the research office administers.
- The research office will receive $650 per FTESIM per fiscal year for computer equipment.
- Supply funds will be estimated from prior year records. Supply funds cannot be carried forward into future years.
- The cost of supplies will be annually adjusted using the Bureau of Labor Statistics Consumer Price Index for all items.[1]

Staff education and training
- $800 per year for every FTESIM for training, education and conferences.
- These funds cannot be carried forward into future years.
- These costs have increased dramatically in the last three years. Therefore, initially the cost of supplies will be annually adjusted using the Bureau of Labor Statistics Consumer Price Index for all items. After three years, education expenditures should be re-evaluated to determine if the amount allotted is sufficient.

The **third step** in the allocation model involves providing flexible funds in proportion to the direct research allocations. These funds are specifically designed to enable sites to better organize and to manage their research office. The flexible spending account is described below.

Flexible spending account
- Research offices will be given an additional administrative allocation equivalent to 3% of the VA-funded research funds administered per year.
- The administrative allocations will be distributed concurrently with research allocations sent from Central Office to the site. Therefore, this allocation reflects the current year's research.
- Any funds that are not spent in a given fiscal year could be carried forward into future fiscal years.
- The Associate Chief of Staff for Research (ACOS/R) and AO are encouraged to work together to budget these funds. However, the ACOS/R has final discretion over these funds, with the stipulation that funds be used to support research.
- These funds must be accounted for and are subject to audit by ORD.

Finally, as with any allocation model, a few additional points must be noted. These are listed below.

Other points
- This allocation model adheres to VHA Directive 1200. As such, the Veterans Equitable Resource Allocation (VERA) is responsible for any fees charged by the affiliate for the IRB or IACUC. In addition, VERA is responsible for equipment maintenance fees.
- This allocation model does not allocate funds specifically for large capital expenditures, such as developing software or a web site. However, research offices could use VERA funds or their flexible spending account for this.
- The assessment of user fees, taxes and levees on VA-funded research allocations:
  - User fees, taxes and levees are permissible when the funds are used to support goods shared among researchers (i.e., common goods).
  - Is inappropriate when such funds are used to provide broad support to the research office, as this is the intent of the 101 funds.
  - Every research office that wishes to collect user fees, taxes and levees for non-animal research must have a written protocol (accessible to researchers) that defines when user fees, taxes and levees apply.
  - Research offices that collect establish user fees, taxes and levees must account for them.
  - ORD reserves the right to audit research offices.

Potential Risks in Increasing 101 Funds
This model derives funding amounts from empirical estimation of optimal staffing, resources, and training programs to administer a given volume of funded research. Qualitative and quantitative data indicate that current levels are inadequate, and need to be increased. Regardless of the specific formula and the specific amount increase, there are risks inherent in any increase of 101 funds.
- Increasing 101 funding may encourage other research administration funders (VERA and VA Non-Profit Research Foundations) to shift costs to 101 funds. We believe the risk of cost shifting can be minimized by encouraging the development of facility level guidelines for VERA research funding, and by developing accounting systems that track cost shifting between VA and the non-profit foundation so that these costs can be reimbursed by extramural funders. Further details can be found on page 28.
- The second limitation is that to meet the improved staffing, resource and training levels within the current administrative structure, overall 101 funding needs to be increased. This model calls for a 35% increase in ORD expenditures for 101 funds. This money will presumably come from funding less research. However, this project and prior work suggests that the increase in 101 funds could be minimized through regionalization of key administrative functions. This is an unproven idea, and would require further planning and pilot demonstrations. More details are provided on page 28-29.
- The third limitation is that with a new allocation model, the small sites would get more than a doubling in 101 funds. A sudden increase of funds would probably overwhelm these small sites. In particular, it is unlikely that these sites could

expeditiously hire new personnel. To minimize this risk, we recommend working with the office of personnel management to develop and approve position descriptions for IRB/IACUC committee support, database support, fiscal management, etc. Particular attention would need to be placed on the appropriateness of these positions for the research office and the level of pay so that medical centers could offer competitive salaries.

RATIONALE FOR A NEW ALLOCATION METHOD

The VA Office of Research and Development (ORD) currently allocates approximately 7% of its budget to VAHCS in consideration of their research administration activities. These funds are sometimes called "101 funds," after their cost center number. The current allocation method is based on a formula that uses the allocation data from two years prior, and the Initial Target Allowance (ITA). Originally there was also a ±10% cap so that funds would not increase or decrease too radically. Later, this was changed so that there was only a –10% restriction (i.e., decreases greater than 10% would be limited to 10%).

In both the in-depth interviews and the quantitative survey data, we found that the current allocation model has some limitations that are becoming increasingly important. The limitations include the following issues:

1) Allocations are insufficient for most research offices.

2) The current system is based on VA funds allocated for research projects and it cannot be easily modified to reflect the changing costs of research administration.

3) The existing system does not reflect the large fixed costs associated with new regulations. If a medical center wants to build a research program, it needs a minimum number of FTE. Small sites are routinely underfunded. In the short term, this may lead to understaffing and poor quality. In the long term, this may affect VA's ability to hire quality researchers.

4) The current system is based on research allocations from two years prior. This assumes that research allocations are stable over time and that the amount of effort required by the research office is a function of the allocation. In fact these assumptions appear to be largely false. We find evidence to suggest that the number of projects and the complexity of projects drive administration costs.

5) The current system does not provide any flexible funds that can be carried into future fiscal years. Every research office has unique goals and needs. The current allocation system is too rigid. Research offices have no way to plan ahead and to save funds for future needs because unused allocations are swept away each year.

We designed the new allocation model to address the aforementioned deficiencies. In doing so, implicit goals emerged. We would rather these goals be explicit. They are:

1) It should reflect the current costs of research administration.
2) It should be easy for ORD to implement and to update.
3) It should be easy for ORD and research offices to understand.
4) It should not be easy to manipulate.
5) It should provide some stable funding over time to enable long term planning.
6) It should provide a sufficient amount of flexible funds for emergencies and site-specific priorities.

METHODS FOR DEVELOPING A NEW ALLOCATION MODEL

Phase I
The first phase involved in-depth interviews with a diverse group of administrators and researchers at eight sites to understand the current funding situation. The sites were chosen to represent small, medium, and large research facilities. Most were established programs, but one program was just emerging and one, though small, was stable and showing some growth. There was broad geographical coverage—six different VISNs were represented. One site did only basic bench research, several ran primarily clinical trials, and several were involved in highly complex protocols. Some sites conducted research with animals, while others did not. These sites also varied with regard to the number of investigators and the number of Merit Reviews and Career Development awards.

At each site, we interviewed the Administrative Officer (AO), the ACOS/R, the medical center director, and the non-profit institute's director (if a non-profit existed at that site). We also conducted a number of interviews with investigators and administrators in the affiliate. All interviews were recorded with permission and analyzed afterwards.

Phase II
The qualitative interviews provided background information that set the stage for phase II: a quantitative study. Although the current study focused on VA research administration, we actively sought information on research administration that was not specific to VA. Such information is discussed in the footnotes of this report.

After the in-depth interviews, we sent a survey to all research AOs or research program coordinators (n=147). The survey was sent by email from Central Office (CO) with a letter of support from the chief research and development officer. A second survey was sent 2 weeks later with a reminder email that followed a week later. The survey was an Acrobat PDF file and the respondents were instructed to print it, complete it and fax it back to us. We called everyone who did not respond four times, leaving a message each time.

Of the 147 sites, 31 indicated that they conducted no research (VA or non-VA funded research). Three sites stated that another medical center handles their research administration, leaving 113 eligible medical centers. As of September 1, 2002, we received responses from 78 out of 113 (69%). Four cases provided incomplete survey data, leaving a total of 74 (65%) sites in our analysis sample. We have little data on the research operations of the non-respondents.

In the survey, we asked the Administrative Officers detailed questions on personnel. For each employee, we collected information on FTE, title and duties. We asked for the funding source, using an open-ended response so that people could identify any source or mix of sources. These sources were coded by hand to reflect 101 funds, other VA funds (e.g., VERA), non-profit or affiliate funds, 105 funds (i.e., animal research funds), or a mix of funds. We then summed the staff FTE into three categories: 101 funded staff, VA funded research office staff (excluding 105 or non-VA funds), or all research office staff (excluding 105 funds). We also asked about expenditures, number of reviews, staff training, investigator training, and resources.

RESULTS
1. Adequacy of 101 funds

- Key points: Current 101 allocations are insufficient for 101-funds related work.

When we asked the sites about work that falls under the scope of 101 funds, none of the eight programs we interviewed in-depth were surviving on their 101 allocations alone.[2] All of the sites had developed "creative" solutions to meet their budgetary needs. All of the solutions varied.

Our survey data confirmed that the current 101 allocations are insufficient to do work that should be covered by 101 funds. We compared the research office staff paid by 101 funds and the research office staff paid by any funds (101, VERA, affiliate, or non-profit). Of the 76 respondents, the vast majority (82%) had FTE in the research office that were not covered by 101 funds. All of these FTE were involved in 101-funds related work. Six sites (8%) had less than 1 FTE covered by other sources, while 53% (n=40) had 1-4 FTE covered by other sources. 14 (18%) had no FTE paid by VERA, the affiliate or the non-profit. This suggests either that other sources were not available or that they were not necessary. The average difference for FTE paid by 101 funds and all FTE in the research office was 2.3 (Table 1).[3] Also, when we asked the AOs to list their top five concerns, staffing was the most frequently cited concern.

Table 1: All FTE in the research office and those FTE paid by 101 funds*

	FTE by all sources (average)	FTE from 101 funds (average)	Difference in FTE (average)
All 74 sites	6.7	3.9	2.3

* Excludes ACOS/R, 105 funds and people working with the animal facility.

2. Criterion for adequate staff in a research office

- Key points: There is no generally accepted or externally valid criterion for identifying whether a research administration office has a sufficient number of FTE. We identified all FTE who were performing work consistent with what the 101 funds should cover. In some instances, affiliates are paying for these FTE. The criterion we used for identifying the adequate number of staff was FTE paid by any source.

There is no generally accepted or externally valid criterion for identifying whether a research office has a sufficient number of FTE. In fact, identifying a justifiable criterion became one of our biggest challenges.

In our survey, we asked AOs to list all positions in the research office that report to the ACOS/R. They were instructed to include vacant positions but to exclude PIs, the ACOS/R, committee chairs and committee members. For each position, we collected the duties, FTE, pay grade and who pays for position. Except for IACUC committee support, we excluded positions that relate to animal care and to 105 funds. We were able to separate the remaining FTE by payment

source (101 funds, any VA funds, any source). Table 2 lists the average FTE by these payment sources. The quantitative analysis, with support from the qualitative evidence, clearly showed that the current 101 funds are not sufficient for personnel.

More important, however, was the finding that many VA research offices have leveraged their affiliations with the VAHCS, non-profits, and academic affiliates to meet their staffing needs. Using affiliates to cover work that should be paid for by 101 funds has its limitations. It is probable that some small medical centers do not have enough leverage to get help. Moreover, this type of funding can be uncertain from year to year and it may strain the relationship between the research office and the affiliate. Nevertheless, this finding enabled us to define an adequate staffing criterion: the 101 funds should cover all personnel who are performing duties relevant to the research administration staff, defined as current FTE from all sources.

Table 2: FTE in the research office paid by 101 funds, VA funds and all sources*

	FTE from 101 funds (average)	FTE from all VA sources (average)	FTE from all sources (average)
All 74 sites	3.9	6.0	6.7

* Excludes ACOS/R, 105 funds and people working with the animal facility.

3. Definition for research office size

- Key points: We defined the research office size using the number of VA-funded projects. This provides no explicit credit for un-funded work.

Every VA funded project has a fixed administrative cost for paperwork, basic committee support, database preparation, establishing financial records, etc. However, large sites have distinct needs to handle the larger volume of research (e.g., a greater use of information technology). Larger sites also have greater compliance and educational requirements.

We operationally defined size as the number of VA funded projects. Central Office has knowledge of the number of VA funded projects at each site and this number cannot be easily inflated. However, creative administrators could easily inflate the number of un-funded projects.

The potential downside of this approach is that a research office incurs some costs associated with non-funded projects, albeit these projects are less resource intensive. Although un-funded projects neither require end-of-year reports nor fiscal tracking, they may involve additional committee work. This additional committee work, however, is covered as research offices receive funds according the number of IRB and IACUC actions.

Another important point is that research offices will receive flexible funds based on 3% of the research allocations. Larger projects, such as center grants or CSP studies, which may have associated un-funded projects, will generate revenue for the research office through the flexible funds.

Finally, this operational definition only includes VA-funded projects that are processed by the research office. We are aware of some CSP coordinating centers that have their own research infrastructure and do not use the research office. Any projects that are not the responsibility of the research administration office should be excluded when counting the number of VA-funded projects.

4. Relationship between research office size and personnel

> - Key points: Small, medium and large research offices have distinct staffing needs. To compensate research offices equitably, we must understand the relationship between research volume and FTE.

A key issue is the relationship between the number of VA-funded projects and FTE. If our data were to indicate a linear relationship, then we could develop a continuous model in which some proportion of FTE are allocated for every VA-funded project. However, if the data suggest that the relationship is non-linear then we would need to develop other modules, such a group allocation model, that addresses this non-linear relationship.

With the survey data, a regression model suggested a nonlinear relationship between size and all FTE (column 1 of Table 3). However, this might reflect variation in the work related to the IRB and IACUC support. In fact, when we excluded the FTE for the IRB or IACUC, we see a linear relationship (column 2 of Table 3).

As Table 3 indicates, we found a non-linear relationship between FTE and number of VA-funded projects. However, when we excluded IRB and IACUC FTE, the data indicated that there might be a linear relationship. However, the low R^2 of 0.07 suggests this model is not accurate enough to justify financial decisions. Therefore, we chose not to rule out a non-linear relationship.

Table 3: Regression model showing the relationship between research office FTE and VA funded projects

	Research office FTE[1]	FTE excluding IRB and IACUC
VA funded projects in 2002	0.19	0.03
	(7.87)**	(2.14)*
VA funded projects squared	-0.001	--
	(7.08)**	--
Constant	1.81	1.08
	(2.34)*	(2.01)*
Observations	61	61
R-squared	0.52	0.07

[1]Includes funding from all sources
* significant at 5%; ** significant at 1%
Absolute value of t statistics in parentheses

As we could not rule out a non-linear relationship, we developed a group allocation model. Developing a group allocation model required us to define the boundaries between small, medium and large research offices. Unfortunately, the regression in Table 3 does not provide information that can be used to classify research offices by size. Creating general categories of research office size is somewhat arbitrary, but it can affect the model's ability to provide a sufficient number of FTE.

To define small, medium and large research administration offices, we tried nine different classification strategies. The goal was to identify a classification strategy that accounted for the most variance between research offices. We measured their ability to account for variance by fitting a regression model for each combination of size. The classification strategies and their ability to account for variance in FTE are listed in Table 4. A higher R^2 means that the classification strategy accounted for more variance and more accurately describes the FTE-funded projects relationship.

Table 4: Alternative classifications for research office size and the classifications' ability to account for variance in FTE

Research office size considerations	FTE[1]	FTE[2]
3 category classifications	R^2	R^2
Small <10, Medium>= 10, Large>=60	0.45	0.10
Small <15, Medium>= 15, Large>=60	0.45	0.10
Small <20, Medium>= 20, Large>=60	0.45	0.10
Small <10, Medium>= 10, Large>=55	0.45	0.08
Small <15, Medium>= 15, Large>=55	0.45	0.08
Small <20, Medium>= 20, Large>=55	0.44	0.09
Small <10, Medium>= 10, Large>=50	0.41	0.04
Small <15, Medium>= 15, Large>=50	0.41	0.04
Small <20, Medium>= 20, Large>=50	0.39	0.05

[1] FTE includes all FTE in research office paid by all sources
[2] FTE is the research office FTE, excluding IRB or IACUC support personnel

Table 4 suggests that the first three size classifications provided the best fit. The table indicates that fit was most influenced by how we defined a large site.[4] With the top three size classifications, we simulated FTE for all VA research offices. We compared the simulated FTE to the research offices' FTE from all funding sources. We chose the size classification that yielded the best fit. This was:
- Small site: <10 VA funded projects
- Medium site: =>10 and <60 VA funded projects
- Large site: =>60 VA funded projects.

5. The effect of regulatory burden

> - <u>Key points</u>: A consequence of regulatory burden is that research offices, no matter how small, have some fixed costs. This translates into a minimum number of FTE required in the research office.

One of our goals was to develop an allocation model that could be updated or modified in the future. To identify likely changes in the future, we considered major changes in the past few years. Two of the important changes have been: 1) increasing research complexity and 2) increasing regulatory burden.[5-7] Complexity is a function of the variety of research, increasing compliance activities, and increasing regulatory oversight with Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Researchers must be educated on the ethical conduct of research, and the administrative staffs must have greater expertise to successfully fulfill their jobs.

A growing number of policy makers, administrators and researchers believe that regulatory burden is having a profound financial effect on research administration.[8-10] VA researchers and administrators must deal with the regulatory burden of non-VA and VA governmental policies.[11]

Some of the regulations require greater education of administrative and research staff. The need for more stringent compliance places additional burdens on all staff. "While many of these standards began as ancillary requirements that could be supervised by facilities employees, they have rapidly grown into jobs requiring specialists to manage the complex and sometimes bureaucratic laws and regulations that they represent."[12]

Moreover, this effect is not uniform for all health care systems—smaller research offices are disproportionately affected. Why is this the case? First, many of the new regulations (e.g. those related to humans and animal subjects protections) involve additional tasks, such as new reports, and additional record keeping. These additional tasks require personnel. The average small site is less economically efficient than the average large site as they have fewer personnel and are less flexible with handling new tasks. Second, regulations can add burden by requiring personnel to specialize—such as requiring the IRB administrator to be certified. Specialization is associated with higher wages. Large sites are better able to spread these additional costs. This is further exacerbated if specialization requires hiring new people.[13]

When we compared research offices based on the number of VA funded projects, we found substantial fixed costs for institutions with small research offices. This fixed cost is largely related to regulatory burden, and therefore is disproportionately burdensome to smaller programs. In all of our proposed allocation methods, we created line items for costs that need to be updated over time. Therefore, the allocation method can be updated to account for regulatory changes (e.g., training and education, or IRB support) without creating a new allocation method.

6. The effect of research complexity on research administration

> - Key points: Research complexity affects research administration costs by requiring research committee review (i.e., IRB, IACUC, R&D, research safety and biohazards). Large sites need less committee support per action, as they are more efficient.

We found that personnel varied with the number of human subjects and animal subjects protocols, and that administration of IRB and IACUCs varied by research volume. Thirty six percent of large sites used their affiliates' IRB compared to 20% of the small sites. On the other hand, 25% of the small sites used their affiliate's IACUC, while none of the large sites did. The new allocation method takes this information into account. Research offices that use their affiliate's IRB or IACUC do not receive additional FTE for these duties.

A common belief is that one FTE is needed per 300-350 actions. However, our prior research on IRBs associated with VA shows that the relationship between FTE and actions is a function of the size of the IRB. [8] Small IRBs, which had 3-151 actions per year, were significantly more inefficient than large IRBs, which had 860-12899 actions per year. A function of being inefficient is that the smaller IRBs need more personnel than the large IRBs.

Table 5 shows the FTE per action used by small, medium and large IRBs.[8] We used this information to allocate FTE per IRB. We allotted no additional FTE if the number of IRB actions was fewer than 50. We allotted 1 FTE for every 200 IRB actions between 50 and 450, and 1 FTE for every 250 IRB actions over 450. We used the same criteria for IACUC actions because we do not have any data to suggest that committee support for IACUCs is significantly different than for IRBs.

Table 5: Actions per FTE

	Actions per FTE
Small IRBs	46
Medium IRBs	222
Large IRBs	381

Source: Wagner TH, Chadwick G, Cruz A. The cost of operating institutional review boards (IRBs) in the VA. Menlo Park: VA Health Economics Resource Center, 2002.

ALTERNATIVE ALLOCATION MODELS

We developed three alternative models that each address the six points above. All three models use VA funded projects as the operational definition for size. This practice maintains the current preference to support funded work. Central Office has knowledge of the number of VA funded projects and this number cannot be easily inflated.[14] The three models are:

1) Group Model: The Group Model has three tiers—small, medium and large research administration offices. Personnel are then allocated to each level, with additional personnel to support the research committee work (e.g., IRB and IACUC).

2) Continuous Model: The continuous model provides a fixed amount of personnel for each VA funded project, with additional personnel to support the research committee work (e.g., IRB and IACUC).

3) Continuous with Step Model: This model reflects a hybrid of the first two models. The continuous with step model provides a variable amount of personnel for each VA funded project, with additional personnel to support the research committee work (e.g., IRB and IACUC). In addition, large sites get additional personnel.

The three models only differ in their allocation of FTE (see Table 6). However, since other costs, such as education and supplies, are based on FTE, each model has different implications for the total cost. In addition, the models have different incentives for facilities near the breakpoints of our small, medium, and large facility definitions. As we will discuss below, we believe that the continuous model is preferable because it provides the optimal number of FTE when compared to the research office's FTE paid by all sources. The continuous model also sets forth a uniform set of incentives.

Table 6: Calculating FTESIM for research offices (not including IRBs and IACUC support)

	Group	Continuous	Count with step
Small sites	3 FTESIM	2 FTESIM + 0.12 FTESIM per VA project	2 FTESIM + (.15* VA funded projects) –(0.0013*VA funded project squared)
Medium sites	5 FTESIM	Same as small	Same as small
Large sites	10 FTESIM	Same as small	Same as small, plus 4 FTESIM

Note, all other costs, including FTESIM for IRBs and IACUCs is calculated the same way for each method

Fiscal implications of the three models

We estimated 101 costs to VAHCS for FY2002 using the Group Model, Continuous Model and Continuous with Step Model. We then compared these estimates to FY2002 reported 101 allocations in terms of facility allocations, personnel, supplies, education and training, and miscellaneous expenditures. We present results for all three models below.

1. Estimated 101 costs

To calculate the total 101 costs, we first had to calculate a site's average salary. On our survey, we asked total salary expenditures. We divided this by the number of FTE in the research office. The average salary was $58,570. Although the average was reasonable, salaries ranged from $16,610 to $277,854. Both the low and high ends seemed unreasonable. In fact, only four sites had an average salary over $100,000, while 6 sites had an average salary less than $25,000. To deal with the potential outliers, we restricted the salaries to be between $36,038 and $58,074. We tried alternative salary estimates and these are discussed in Appendix B.

Results suggest that the allocation models would increase ORD's support for research 31%-35%. At present, approximately 7% of ORD's budget is spent on research support. The new models would increase that to approximately 9%-10%. Details can be found in Table 7, where simulated funds reflect allocations under the proposed model. Note that Table 7 reports costs for only the 67 sites that reported 101 funds for FY02. Appendix A lists each site's 101 allocations and predicted allocation without station identifiers.

Table 7 shows that the total costs for the three allocation models are relatively similar (range $28.2 million to $29.0 million). However, the three models have very different effects on small, medium and large research offices. The Continuous Model provides fewer resources to small offices and more resources to medium and large offices.

Table 7: Simulated and reported 101 allocations

	101 Allocation* (FY02)	Group Model		Continuous Model		Continuous w. Step	
		$	% Chg.	$	% Chg.	$	% Chg.
Small (n=17)	$1,017,461	$2,852,187	180%	$2,385,091	134%	$2,630,646	159%
Medium (n=39)	$12,703,357	$15,905,353	25%	$16,554,210	30%	$16,432,387	29%
Large (n=11)	$7,724,722	$9,434,006	22%	$10,030,134	30%	$9,748,470	26%
Total (n=67)	$21,445,540	$28,191,546	31%	$28,969,435	35%	$28,811,503	34%

Note: Only includes VAHCS that reported 101 allocations for FY02
*101 allocations as reported by the AO.

2. Implications for personnel

There are no commonly accepted or externally valid criteria to identify the appropriate level of staffing for research administration offices. In the survey, we asked about all research administration staff paid by any source (VA, non-profit, or affiliate). These folks are performing tasks that should be covered by the 101 funds. Therefore we used all FTE working on VA research support as our criterion; this is shown in the second column of Table 8. Table 8 also lists the 101-funded FTE and the FTE provided by the allocation models.

The three allocation models would increase 101-funded FTE by 59%-65% (see Table 8). For our sample of sites, the new group, continuous and continuous with step allocation models would

result in 419, 435, and 430 FTE, respectively, compared to current the 264.3 FTE paid by 101 funds.

Table 8 also shows how the three allocation models would affect the small, medium and large research administration office. The Table provides information on the sum, 25th percentile, median, mean and maximum. This information is particularly important because we wanted to make sure that the new allocation model would be equitable for small, medium and large sites. For the small sites, the three allocation models work well, except for the largest of the small sites. Among the medium sized sites, the continuous model provides the best fit. Among the large research offices, the continuous and continuous with step models are very similar and yield better fits than the group model. However, the largest of the large sites reports 26 FTE in the research office. While the continuous model was optimal for this particular site, it only provided 17 FTE.

Table 8: FTE in research offices

	101 funds	Actual FTE (via survey) All FTE*	Group model FTESIM	Continuous model FTESIM	Continuous with Step Model FTESIM
Small					
Sum	14.7	50.8	52.1	44	47.5
25th per	0	1.5	3	2.4	2.4
media n	0	2.5	3	2.6	2.7
Mean	0.9	3.2	3.1	2.6	2.8
Max	5	9	3.7	3.5	4.1
Medium					
Sum	166.2	246.6	232.8	250.6	242.3
25th per	3	5	5	4.5	4.8
media n	4	6.8	5.4	6	6
Mean	4.3	6.5	6	6.4	6.2
Max	9.5	12.5	9.7	13	11
Large					
Sum	83.3	139.8	134.1	140.6	139.9
25th per	4	9	10.8	11.1	11.6
media n	9	12	12.1	12.2	12.3
Mean	7.6	12.7	12.2	12.8	12.7
Max	13.8	26	14.9	17	15.3

Total	264.3	437.2	419	435.2	429.7
% Chg.	--	65%	59%	65%	63%

*reflects FTE paid by nonprofit or affiliate
Note: All VA funds include 101 funds and medical research funds.
All funds include FTE paid by non-profits and affiliates.

We should also note that any model might decrease the current FTE funded by VERA. However, this will depend on the research office and their relationship with the medical center director. This cannot be predicted *a prioi*, so we did not account for this in our allocation models.

Figures 1 and 2 graphically illustrate the relationship between current FTE and the allocation models. Figure 1 shows the actual numbers. Given all of the data points, this can be difficult to interpret. Therefore, we also plotted trendlines (3 period moving averages) in Figure 2 to give a better impression of the effects of the allocation model.

Figure 1: The research office's current FTE and predicted FTE
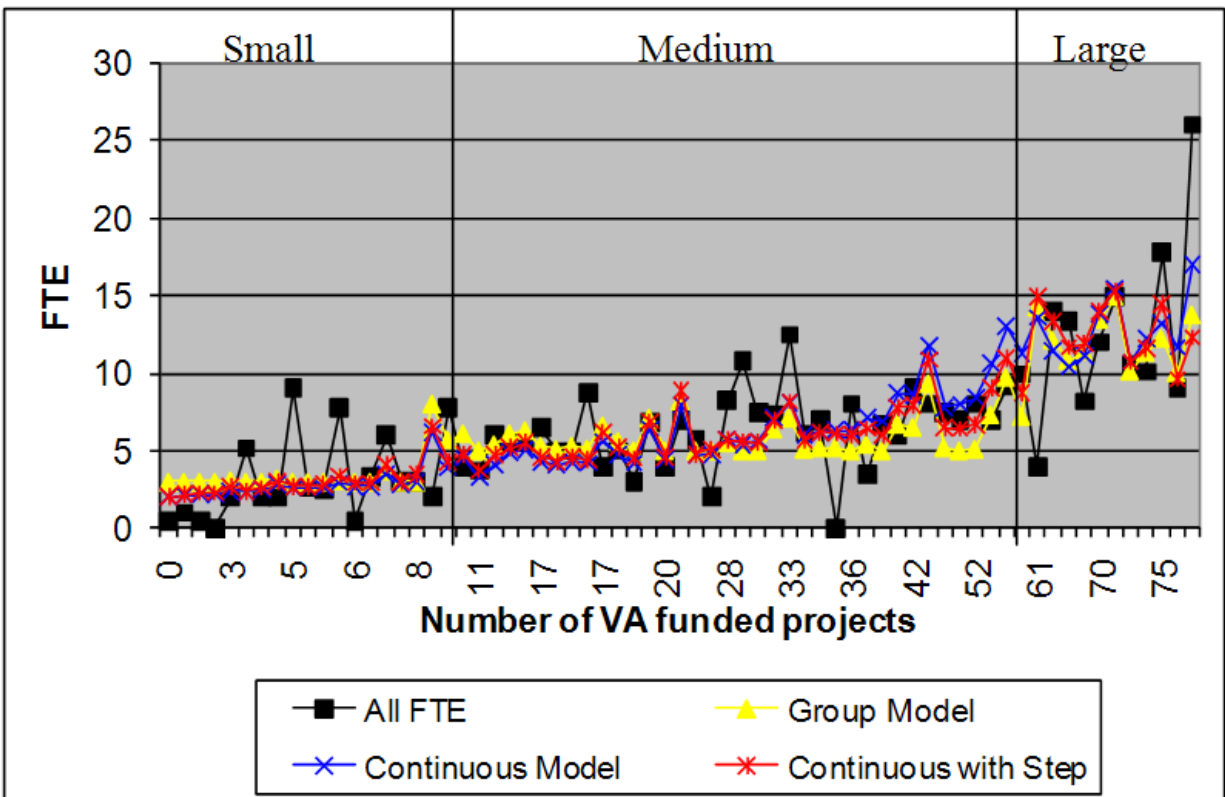
Note: FTE is a function of the core personnel and personnel based on IRB and IACUC effort.

Figure 2: The research office's current FTE and predicted FTE (with smoothing)
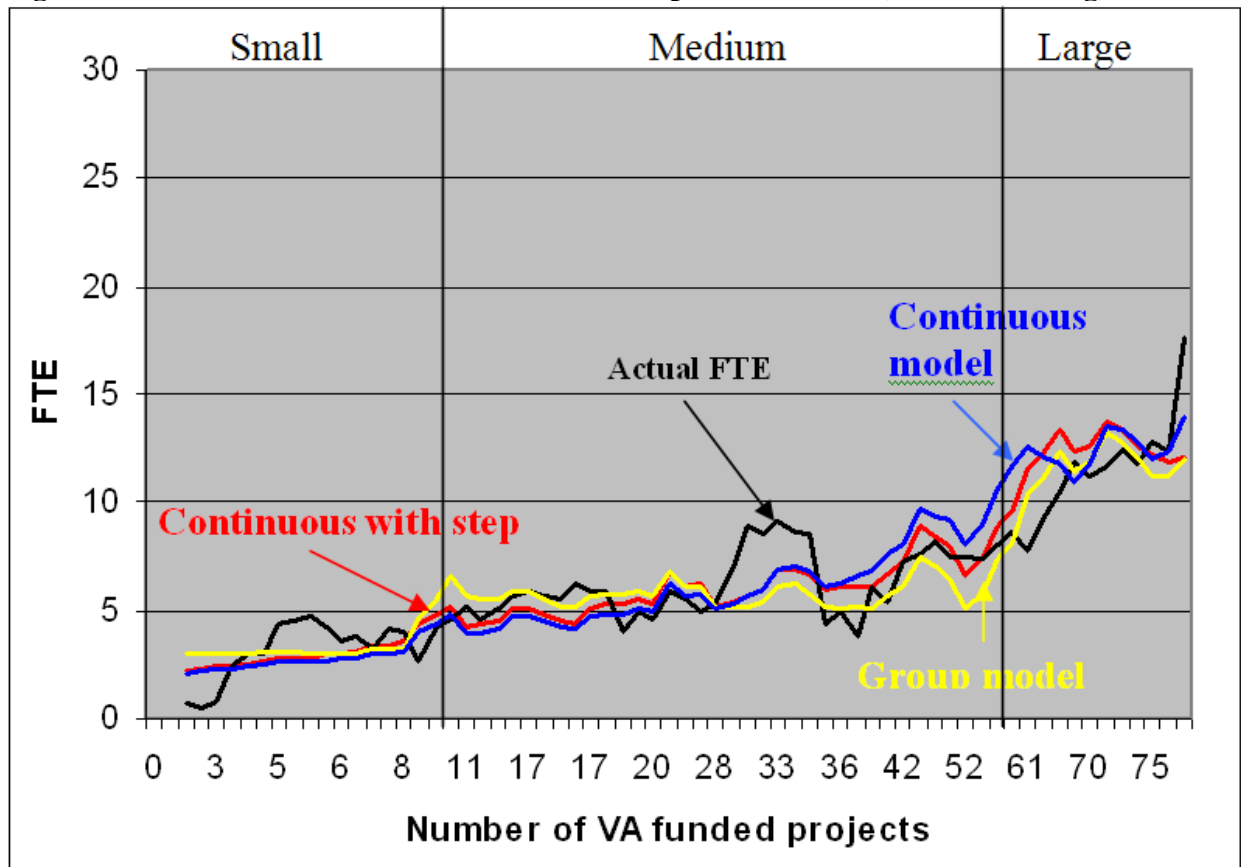
Note: FTE is a function of the core personnel and personnel based on IRB and IACUC effort.

3. Implications for supplies

The proposed supply calculations were based on supply expenditures, and are identical for all the allocation methods. Our data indicate that expenditures for supplies varied with the number of VA funded projects and the number of committee actions (initial reviews, continuing reviews and amendments). The data show that the cost per action is relatively stable over time at approximately $500 per VA-funded study and $50 per action.

In the three allocation models, we estimated the cost of supplies as a function of VA funded projects ($500 per project) and actions ($50 per action). We then included a personal computer per FTE. The cost per computer was $650, which is calculated as a $2000 purchase with a 3-year straight-line depreciation and no salvage value. We believe that future increases in supply funds should be based on the Consumer Price Index.

The three allocation models would provide supplies based on the workload and staffing. Supply expenditures and simulated supply funds for FY02 are shown in Table 9. The new allocation models would result in a 16% decrease in funds for supplies. Sites that wanted to spend more on supplies could use the flexible funds. Again, as noted above, the funds are for basic supplies not

covered by VERA. These funds are not intended to finance core lab facilities or other capital investments.

Table 9: Current expenditures and simulated funds for supplies (FY02)

| | Supply Expenditures | Simulated supply | | |
| | | | Continuous | Continuous |
	(FY02)	Group Model	model	with Step
Small				
Sum	$64,751	$114,365	$109,100	$109,100
Mean	$4,981	$6,727	$6,418	$6,418
Medium				
Sum	$1,503,666	$1,301,920	$1,313,490	$1,313,490
Mean	$39,570	$33,383	$33,679	$33,679
Large				
Sum	$362,625	$827,215	$831,440	$831,440
Mean	$32,966	$75,201	$75,585	$75,585
Total				
Sum	$1,931,042	$2,243,500	$2,254,030	$2,254,030
Mean	$31,146	$33,485	$33,642	$33,642

4. Implications for staff education and training

The three proposed allocation models would increase education and training funds 94%-101%. Table 10 shows the current and simulated expenditures for education (FY02).

Staff members need training and education. This need is paramount with the new confidentiality regulations, including the Health Insurance and Portability Accountability Act (HIPAA), and continued specialization. Based on reported training expenditures for FY00, FY01 and FY02, we estimated the cost of training as a function of FTE. This cost per FTE is the same for all the proposed allocation methods.

Our survey indicated that not all sites provide education. In FY2001, 31% of the research offices provided no training for staff. With changes in regulations, accreditation for IRBs, and increases in research complexity, all research offices need ongoing training.

The survey data indicate that training costs have been increasing in the past three years. In FY00, the average amount spent on training per FTE was $389. This increased to $460 (an 18% increase) in FY00 and jumped an additional 75% to $854 in FY02. Research on IRBs shows that the training costs approximate $1000 per FTE; however, IRB training is probably more extensive

than other staff functions. Therefore, we used a cost of $800 per FTE per fiscal year for the allocation method.

Given the rapid changes in the past three years, it is unclear how these costs should be adjusted in future years. One option would be to allow for a 10% annual increase for the next five years, at which point these costs would be reevaluated.

Table 10: Current and simulated expenditures for education (FY02)

	Actual from survey	**Group Model**	**Continuous model**	**Continuous with Step**
Small				
Sum	$37,713	$41,680	$35,200	$35,200
Mean	$4,190	$2,452	$2,071	$2,071
Medium				
Sum	$100,106	$186,240	$200,480	$200,480
Mean	$3,850	$4,775	$5,141	$5,141
Large				
Sum	$35,091	$107,280	$112,480	$112,480
Mean	$3,509	$9,753	$10,225	$10,225
Total				
Sum	$172,910	$335,200	$348,160	$348,160
Mean	$3,842	$5,003	$5,196	$5,196

5. Other needs

Research offices have purchasing responsibilities. According to our survey data, the number of credit card purchases varied from 0 to 4735 purchases per VAHCS. The number of VA funded projects was the best predictor of these expenditures. By using VA size to determine the fixed number of FTE, we believe our current system accounts for these duties. Otherwise, additional support can be paid for with the flexible funds.

Two of the sites in our sample rented office space for the research office. As this allocation model does not cover rent, it will have to be negotiated with ORD on a case-by-case basis.

Two sites predicted that they would have to start an IRB due to their affiliate's refusal to undergo the NCQA IRB accreditation process. These sites will have to work with ORD to provide sufficient funds for IRB support staff during the start up period.

Relative Merits of the Continuous Model

The primary goal for a new allocation model is to adequately fund research administration. On that level, the Continuous Model does the best job. Yet, there are other criteria upon which the

models could be judged. In Table 11 we list the goals of the study and differences in the three allocation models.

As Table 11 shows, the continuous Model does as well as or better than the other allocation models.

Table 11: Goals for a new allocation model and relative merits of the alternative models

Goals	Continuous Model	Group Model	Continuous with Step
1) Reflect the current costs of research administration.	Most closely matches research offices needs	Overfunds small sites and underfunds large sites	Overfunds small sites and underfunds large sites
2) Easy for ORD to implement and to update.	All three models are similar.	All three models are similar.	All three models are similar.
3) Easy for ORD and research offices to understand.	Easy to understand	Easy to understand, but may instill some unusual incentives	Hardest to understand.
4) Not easy to manipulate.	All three models are similar.	All three models are similar.	All three models are similar.
5) Provide stable funding over time.	Stability is based on the number of VA-funded projects.	Has inherent problems; requires a waiting period for shrinking sites	Has inherent problems; requires a waiting period for large sites that are shrinking.
6) Provide flexible funds for emergencies and site-specific priorities.	All three models are similar.	All three models are similar.	All three models are similar.

One area that is particularly important is the need for the model to provide stable funding over time. Support for research office staff is based on the number of VA funded projects. From these data, we categorized research offices as small, medium and large. The Group Model uses this three-tier classification system to calculate the FTE. This Group Model provides consistency for the research office staff with small fluctuations in the number VA funded projects. The downside is that there are "cliffs" in funding, such that ORD support changes dramatically with the 10th and 60th VA funded projects.

Cliffs are less of a concern for growing sites. However, they are a major concern for sites whose number of VA funded projects drops below the cliff (the 'shrinking' sites, referred to in Table 11). For instance, imagine a site with 63 VA funded projects in FY00, 62 in FY01 and 59 in FY02. In FY00 and FY02, the site would be considered a large site and receive 10 core FTE. In FY02, it would be considered a medium site and would receive support for 5 FTE. In other words, it would lose 5 FTE. This could have devastating consequences on the site's staff and on the quality of the office, especially if this is a one-year aberration.

A solution for this is that sites that are reclassified at a smaller size are observed for a 2-year period. This is analogous to a waiting period. If their size continues to decrease in that time, then they would be reclassified and their funding changed.

The Continuous with Step model only has one cliff. Nevertheless, large sites that fall below the large classification would still need the waiting period. The Continuous Model has no cliffs, and is therefore our preferred choice.

POLICY ISSUES AND AREAS FOR IMPROVEMENT

Our data collection and analysis has found several important issues that are not addressed by our proposal. We see these as very important tangential issues. Although they will affect a VAHCS' financial resources, they are outside the scope of the current project and should be handled in the future.

Cost sharing with VERA[15]

According to VHA directive 1200 (adopted November 1, 2001), 101 funds are <u>not</u> intended to support activities funded by the medical care appropriation or direct research project allocations. The cost of clinical staff, including physician investigators and the Associate Chief of Staff for Research (ACOS/R), is paid by the medical care appropriation (VERA). VERA funds are supposed to support physician researchers, facility charges for maintenance, utilities, IRM support, and administrative support for committee review and record keeping.

Although VERA is designed to support research and the research office, in practice this rarely happens. In our survey data, 82% of the sites reported no VERA dollars in FY01 or FY02. In addition, according to our survey, the two most common problems with VERA are the support for equipment maintenance and inadequate support by IRMS. The VERA system has guidelines for allocating research funds to VISNs. Guidelines for allocating money to medical centers within each VISN exist. However, the execution of facility-level allocations has room for interpretation and is left up to the VISN. VERA research funds provided to the medical center are rarely used to support the research office. Only one of the 74 sites studied that has a written policy for allocating VERA money to the research office.

Based on our interviews, we believe that the lack of a standard written policy for distributing VERA funds to VAHCS and to research offices in particular, is a major problem for research offices. First, research offices rarely see any VERA funds. When they do receive support, especially in-kind support, the AOs often report that the support is limited, of poor quality, or does not meet the needs of the research office.[16] Without stable VERA funds, research offices have looked to their affiliate and non-nonprofit for support.[17] Our survey data show that the affiliates and the non-profits provide <u>substantial</u> support for the research office. Whether this reflects problems only with VERA or whether it reflects problems with VERA and insufficient 101 funds is unclear.

We find substantial evidence to suggest that any allocation model would benefit from a clearly written policy for distributing VERA funds to VAHCS and to the support of research offices. If the costs of the research administration are supposed to be shared, failure to do so has direct implications for the research office's performance and quality.

Cost sharing with the non-profit research foundation

Many VAHCS have cooperative relationships with their non-profit. The non-profit often provides staff support. In return, the non-profit often does not have to pay for IRB or IACUC review or space. While implicit cost sharing between these entities may be beneficial for both, if this cost sharing is made explicit, then other entities, such as NIH, will pick up the costs. Given that the non-profit is administering non-VA grants (including NIH, DOD, CDC or drug company funds), an explicit cost accounting system should be considered so that VA does not support non-

VA research. If the non-profit had to pay rent, for example, the revenues would go to the VAHCS and research office. The non-profit could then recoup these costs from the funder (e.g., NIH or the drug company).

Is the proposed allocation method optimal?
It is recommended that any changes to the current 101 allocation model be evaluated. Issues to consider would include satisfaction with the new allocation method, effects on AO, ACOS/R and researchers, and effects on the relationships with the medical center, affiliate and non-profit.

In particular, it is strongly recommended that future research consider economies of scale. Preliminary evidence in this study and evidence from a recent IRB report by Wagner and colleagues[8-10] suggest that there may be financial benefits to consolidating the research offices across VAHCS into collaborative groups.

Efficiency through regionalization
VA is a unique research system. This is especially true when effecting change in policy. What would be a small policy change for an individual research office or an individual IRB could have massive ripple effects in the VA system. Given the number of research administrative offices, the VA may benefit from considering alternative organizational approaches.

This study found that if ORD adopted the Continuous Model, allocations to research offices would have to increase by approximately 35%. In absolute terms, that reflects an increase of approximately $8.5 million per year. For a system that is globally capitated, an increase of this magnitude means that cuts would need to be made elsewhere.

A particularly worthy area for future study is the development of regional centers for research administration. In particular, this inquiry relies on an analysis of the efficiency of the current system and whether larger research administrative offices are more efficient than small research offices (economies of scale). The hypothesis is that if the efficiency can be improved then fewer dollars are required to accomplish the same work. Any savings could then be reinvested, whether that involves providing more research support or care to veterans.

A number of indicators suggest that large research administrative offices are more efficient than small research offices. In the in-depth qualitative interviewers, we found that small sites were having difficulty responding to requests from headquarters (increasing regulatory burden). This was a more common problem in the small sites than in the large sites.

Another theme that emerged was the lack of opportunities and of a professional administrative culture at small sites. Large sites were growing, providing more opportunities for professional growth and development. In addition, having more employees is important for building a professional culture. Some of the very small sites have attempted to build a virtual network with each other, but they still lack the close proximity and the opportunistic chances to share ideas. These are particularly important issues for retaining skilled and motivated employees in a field that is becoming more complex.

Finally, our past study on IRBs[18] found clear and robust evidence to suggest that large IRBs are significantly more efficient than small IRBs. Figure 3 shows the cost per action for small, medium and large IRBs.

There are potential downsides to regionalizing the research administration. For example, local control and onsite representation are important to ensure monitoring, responsiveness to researchers and patients, and in the case of IRBs, reflect local values in human subjects discussions. Hybrid approaches, with some administrative and IRB/IACUC functions regionalized and others not, may be required. We recommend that ORD commission a study to investigate the costs and benefits of these issues more thoroughly.

Figure 3: Estimated cost per action
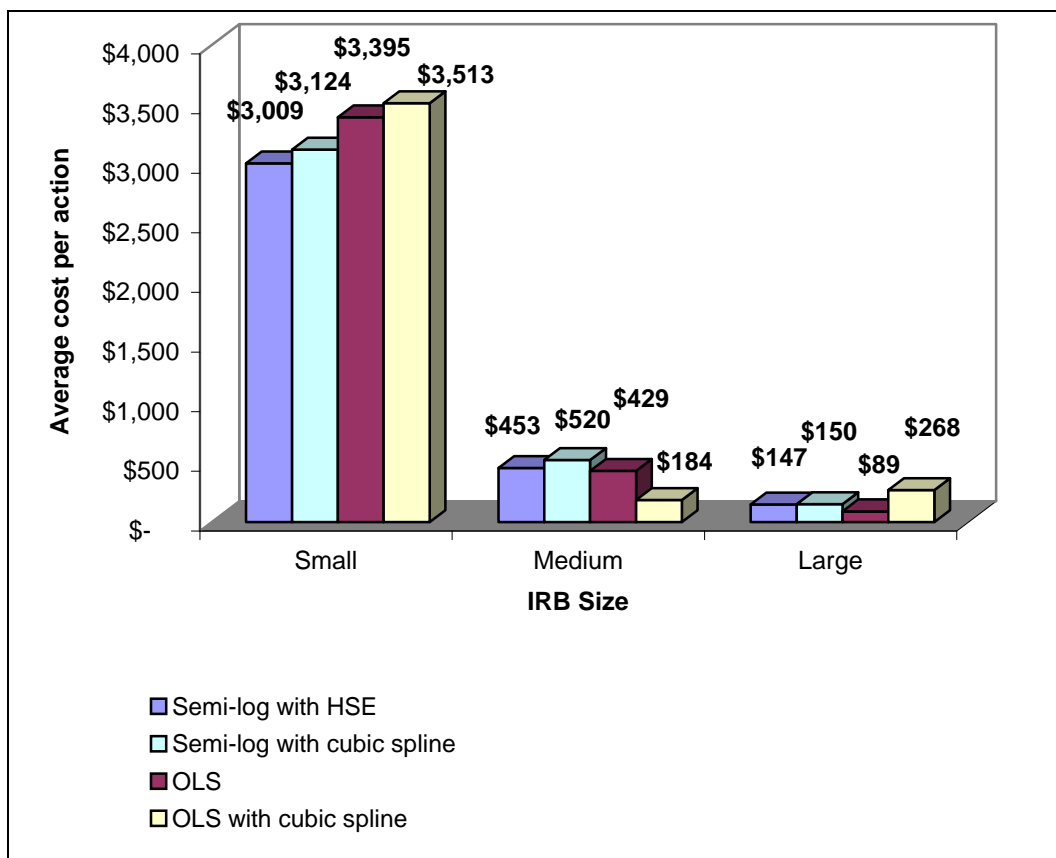
Source: Wagner TH, Chadwick G, Cruz AME. The cost of operating institutional review boards (IRBs) in the VA. Menlo Park: VA Health Economics Resource Center, 2002.
Note: Estimates from regression model, other values held at mean.
Costs are in 2001 dollars
HSE is heteroskedastic smearing estimator

NOTES

1.   Consumer price index can be found at http://146.142.4.24/cgi-bin/surveymost?cu.
2.   Considering all funding, which includes help from the non-profit (if present), two of the programs stated they were severely understaffed; three programs were somewhat understaffed (though one of these only because of the accreditation process); and, one program would have had severe understaffing except for the contributions of its nonprofit. All eight stations had active nonprofit corporations, though only three of the nonprofits had revenues of over one million dollars (36 of the 88 existent VA nonprofits had FY2000 revenues over one million dollars). All eight stations were affiliated with a university medical school though one of these affiliations was basically moribund as the school was very far away. Relationships with the affiliates varied: one basically nonexistent; two reported strained relationships; three had close relationships; and two had excellent relationships where the universities had actually given significant funds for lab and building renovations.
3.   These numbers suggest that many sites have a symbiotic relationship with their affiliate and non-profit. While cost sharing between these entities may be beneficial for both, if this cost sharing is made explicit, then other entities, namely NIH, will cover the costs. If the non-profit had to pay rent, for example, the revenues would go to the VAHCS and research office. The non-profit could then recoup these costs from NIH.
4.   We created an alternative classification that had four categories (Small <10, Medium>= 10 & <50, Medium large >=50 &<70, and Large >=70). This four-category classification provided a better fit for all FTE, but it provided a worse fit when assessing the FTE excluding IRB or IACUC support personnel.
5.   Slater EE. IRB reform. N Engl J Med 2002; 346:1402-4.
6.   OIG. Institutional review boards: a time for reform. Rockville, MD: Office of the Inspector General, Department of Health and Human Services, 1998.
7.   Woodward B. Challenges to human subjects protections in US medical research. JAMA 1999; 282:1947-1952.
8.   Wagner TH, Cruz AME, Chadwick G. The cost of operating institutional review boards (IRBs) in the VA. Menlo Park CA: VA Health Economics Resource Center, Final Report for HSR&D MRR-00-019, 2002.
9.   Wagner TH, Chadwick G, Cruz AME. The cost of biomedical institutional review boards associated with the VA. 2002.
10.   Wagner TH, Cruz AME, Chadwick G. Economies of scale in biomedical institutional review boards. 2002.
11.   The General Accounting Office (GAO) published a listing of 60 federal regulations that affect researchers. These have a cumulative negative impact on researchers and research administration. Duplication, conflicting requirements from multiple agencies, focusing on process rather than results, lack of communication and education are the primary results. In the 1990s, the National Institutes of Health (NIH) undertook a variety of initiatives to increase the efficiency and effectiveness of its grants administration and internal administrative operations and in the last several years has been working to do the same for the research community by reducing regulatory burden. Five areas that were specific to researchers were chosen as the initial focus-human subjects protection, animal care and use, research integrity, financial conflict of interest, and the disposal of hazardous wastes.

Concerted efforts by NIH and the Department of Health and Human Services (DHHS) to reduce regulatory burden are already yielding significant change and improvements. Some of these efforts have directly and indirectly affected the VA. For instance, just-in-time protocol review was a NIH program that was recently adopted by VA. Also, the process of getting federal authority to run studies with human subjects was streamlined significantly, resulting in a single Federalwide Assurance (FWA). Other NIH examples include changing the semi-annual inspection of animal labs to annual inspections and the NIH proactive compliance site visits. While NIH efforts are effective and their coordination with other agencies ongoing, there is still a great deal to be done and they are only one part of the problem. Many of the agencies creating regulatory burden do not have regulatory reform as a priority. Until greater coordination exists, regulatory burden (defined as governmental legislation, regulation, or policy that could be made more efficient without diminishing the intended level of protection) will probably only worsen.

12. Goldman CA, Williams T, Adamson DM, Rosenblatt K. Paying for university research facilities and administration. Santa Monica: RAND, 2000.

13. In addition, our survey data show that compliance with CO reporting guidelines and special requests was the second most frequently cited problem. AOs reported that they need more staff to keep up with reports to CO.

14. The downside of this is that a research office incurs costs associated with non-funded projects, albeit these projects are less resource intensive. Unfunded projects may require IRB review, but they neither require end-of-year reports, nor fiscal tracking.

15. There are differing philosophies for funding research administration. NIH uses the most widely known method, in which NIH pursues a cost-sharing plan with academic institutions. The premise is that these institutions would conduct similar research in the absence of NIH funds, and that the presence of NIH funds expedites research. In 1996, NIH took a hard stance on this issue by setting a limit on how much it will reimburse academic institutions for their administrative costs.

16. An example is the requirement that VA employees, including researchers, purchase IBM compatible machines with Windows 2000. The systems used by most researchers grew out of their relationship with the affiliate. In some instances this is information technology based on the Macintosh. The Information Resources Management Service (IRMS) of the medical center has not been able to support the programs used in research; in many if not most cases, research offices have had to hire their own information technology people.

17. Our interviews also suggest that the lack of a written policy may have other consequences, such as making a rift between the research office and the VAHCS director's office.

18. Wagner TH, Chadwick G, Cruz AME. The cost of operating institutional review boards (IRBs) in the VA. Menlo Park: VA Health Economics Resource Center, 2002.

APPENDIX A: 101 ESTIMATES BY INDIVIDUAL VAHCS

101 allocations compared to allocations based on Group, Continuous and Continuous with Step Models

	Studies[1]	101 Allocations			Estimated allocations (FY01)			Estimated allocations (FY02)		
		FY00*	FY01**	FY02**	Group Model	Continuous Model	Continuous with Step	Group Model	Continuous Model	Continuous with Step
1	0	$0	$35,449	$3,500	$112,814	$75,326	$75,326	$113,581	$76,093	$76,093
2	1	$28,880	$28,880	$32,709	$115,008	$81,269	$84,873	$114,930	$81,191	$84,795
3	2	$0	$12,833	$9,706	$115,199	$85,209	$88,812	$115,223	$85,232	$88,836
4	2	$0	$0	$6,806	$182,000	$134,381	$140,188	$179,862	$132,242	$138,050
5	3	$1,036	$6,615	$0	$195,404	$153,738	$171,160	$193,647	$151,981	$169,403
6	3	$107,949	$107,948	$48,940	$188,863	$153,148	$153,148	$188,472	$152,758	$152,758
7	4	$41,475	$43,995	$47,970	$139,187	$117,820	$121,948	$139,261	$117,894	$122,023
8	5	$0	$35,927	$50,332	$141,950	$125,802	$133,586	$151,841	$135,692	$143,477
9	5	$391,456	$0	$0	$225,240	$201,431	$207,238	$235,789	$211,979	$217,786
10	5	$0	$40,220	$27,120	$143,686	$125,677	$130,034	$139,292	$121,284	$125,641
11	5	$59,660	$76,779	$56,573	$187,274	$163,465	$175,080	$188,179	$164,369	$175,984
12	6	$0	$222,976	$227,253	$206,357	$194,452	$223,489	$246,424	$234,520	$263,557
13	6	$0	$0	$0	$120,034	$108,788	$115,996	$117,929	$106,683	$113,891
14	6	$47,256	$44,926	$63,284	$197,221	$179,363	$190,978	$191,318	$173,461	$185,076
15	7	$164,085	$116,486	$130,918	$163,820	$156,322	$177,945	$182,531	$175,034	$196,656
16	7	$145,302	$169,315	$154,277	$164,868	$155,256	$164,578	$177,535	$167,923	$177,245
17	8	$171,390	$171,390	$158,073	$173,644	$173,644	$196,646	$176,373	$176,373	$199,375
18	10	$119,840	$119,837	$147,546	$464,515	$375,666	$394,830	$469,683	$380,834	$399,998
19	10	$130,914	$67,820	$74,180	$241,901	$174,422	$188,838	$242,952	$175,473	$189,888
20	11	$169,120	$169,833	$178,120	$404,904	$309,665	$327,087	$401,106	$305,868	$323,290
21	11	$138,864	$163,692	$162,593	$221,129	$157,399	$171,814	$218,098	$154,369	$168,784
22	14	$380,220	$226,673	$219,749	$312,986	$249,950	$278,173	$332,296	$269,261	$297,484
23	15	$0	$118,000	$155,000	$266,676	$221,690	$232,501	$277,877	$232,891	$243,703
24	15	$361,400	$165,342	$188,887	$421,858	$351,065	$374,082	$441,998	$371,206	$394,223
25	17	$218,008	$218,000	$216,100	$292,296	$247,703	$260,646	$291,784	$247,191	$260,134
26	17	$244,678	$195,125	$202,116	$267,953	$224,642	$233,014	$286,565	$243,254	$251,626
27	17	$227,412	$215,303	$228,419	$263,029	$225,540	$236,352	$261,727	$224,239	$235,050
28	17	$321,045	$281,395	$280,282	$374,075	$320,504	$332,118	$393,025	$339,453	$351,068
29	17	$227,208	$245,575	$246,093	$351,260	$306,786	$332,600	$364,257	$319,783	$345,598
30	18	$190,927	$181,449	$225,044	$331,541	$288,584	$311,724	$333,326	$290,369	$313,509

	Studies[1]	FY00*	FY01**	FY02**	Estimated allocations (FY01)			Estimated allocations (FY02)		
			101 Allocations		Group Model	Continuous Model	Continuous with Step	Group Model	Continuous Model	Continuous with Step
31	18	$172,352	$187,343	$201,114	$293,389	$254,129	$268,417	$296,082	$256,821	$271,109
32	19	$229,415	$0	$0	$350,090	$323,849	$341,868	$396,533	$370,291	$388,310
33	20	$143,565	$244,000	$244,000	$313,019	$283,298	$292,915	$321,077	$291,356	$300,973
34	22	$224,561	$216,336	$243,398	$415,866	$404,619	$440,657	$434,805	$423,559	$459,597
35	22	$323,552	$235,821	$248,296	$355,075	$337,218	$343,025	$381,570	$363,713	$369,520
36	23	$361,743	$285,000	$257,300	$366,008	$354,103	$371,525	$346,937	$335,032	$352,454
37	28	$388,378	$409,898	$501,562	$383,194	$398,557	$393,581	$449,271	$464,634	$459,658
38	28	$516,360	$516,356	$312,922	$276,068	$291,063	$298,271	$295,879	$310,874	$318,082
39	30	$236,720	$236,724	$316,820	$283,181	$305,674	$302,070	$303,001	$325,494	$321,890
40	31	$467,292	$349,978	$353,503	$492,931	$534,598	$528,791	$521,431	$563,098	$557,291
41	33	$412,560	$320,364	$367,764	$443,839	$481,327	$484,931	$470,515	$508,003	$511,607
42	33	$286,160	$305,116	$310,306	$277,999	$311,738	$300,927	$300,793	$334,532	$323,720
43	33	$381,455	$337,095	$413,056	$413,855	$473,379	$473,379	$431,010	$490,534	$490,534
44	34	$282,402	$342,476	$375,597	$435,778	$501,254	$489,639	$457,366	$522,842	$511,227
45	36	$413,881	$403,152	$415,424	$433,791	$511,172	$493,750	$446,704	$524,086	$506,663
46	39	$433,608	$433,608	$438,700	$469,832	$547,681	$516,641	$427,401	$505,250	$474,209
47	41	$428,076	$0	$0	$324,232	$396,311	$363,473	$321,078	$393,157	$360,319
48	42	$367,401	$346,452	$349,995	$415,962	$502,488	$464,857	$431,261	$517,787	$480,155
49	42	$261,841	$338,169	$364,111	$565,081	$690,081	$649,429	$558,202	$683,203	$642,551
50	46	$293,794	$301,876	$1,476,722	$758,566	$907,376	$855,109	$798,804	$947,614	$895,347
51	47	$563,160	$423,476	$441,950	$366,553	$468,484	$419,404	$397,462	$499,394	$450,313
52	50	$576,342	$453,428	$445,744	$453,865	$632,437	$539,519	$472,641	$651,213	$558,295
53	52	$412,419	$401,199	$490,855	$467,280	$641,224	$554,082	$497,950	$671,893	$584,751
54	52	$418,874	$386,047	$463,846	$500,934	$634,272	$575,839	$578,044	$711,382	$652,949
55	52	$678,304	$509,752	$504,018	$825,702	$1,022,131	$905,983	$805,643	$1,002,072	$885,924
56	59	$581,944	$581,936	$642,225	$679,984	$892,131	$761,369	$449,199	$661,346	$530,584
57	61	$742,083	$751,486	$754,513	$1,133,794	$1,098,080	$1,173,576	$1,160,139	$1,124,424	$1,199,920
58	61	$547,926	$490,000	$500,000	$688,642	$662,401	$734,477	$690,405	$664,163	$736,239
59	63	$682,992	$682,979	$606,525	$873,856	$851,586	$922,078	$925,263	$902,993	$973,485
60	64	$593,376	$554,668	$570,746	$821,114	$806,164	$844,872	$832,694	$817,743	$856,451
61	70	$630,534	$631,329	$688,498	$825,312	$841,001	$848,556	$637,444	$653,133	$660,688
62	71	$898,263	$801,284	$810,188	$1,110,391	$1,138,279	$1,129,273	$905,530	$933,419	$924,413
63	71	$1,212,686	$941,292	$686,729	$690,680	$719,540	$719,540	$730,727	$759,586	$759,586
64	74	$563,450	$543,237	$586,193	$904,123	$954,807	$921,888	$951,570	$1,002,254	$969,335
65	75	$757,100	$670,562	$706,605	$1,024,075	$1,081,513	$1,154,297	$1,061,287	$1,118,725	$1,191,508
66	81	$541,926	$644,338	$670,031	$765,941	$848,729	$749,506	$805,746	$888,534	$789,312

	Studies[1]	FY00*	FY01**	FY02**	101 Allocations		Estimated allocations (FY01)			Estimated allocations (FY02)		
					Group Model	Continuous Model	Continuous with Step	Group Model	Continuous Model	Continuous with Step
67	94	$692,040	$1,120,269	$1,144,694	$904,324	$1,028,034	$858,656	$733,201	$856,911	$687,533

[1] Number of VA funded projects reported by RDIS
*As reported in RDIS for FY00
**Self-reported by Administrative Officer for FY02

APPENDIX B: SENSITIVITY ANALYSIS

Our main calculations were based on site-specific salaries that ranged from $36,038 and $58,074. In the sensitivity analysis, we recalculated the total cost using two other salary estimates. The first was a site-specific salary estimate with a limit of $80,000. The second was based on using $46,280 (i.e., the national median).

Table B1 shows how these different salary estimates affect the total cost. Using site-specific salaries with a cap of $80,000 yielded a larger total cost estimate of approximately $30 million (a 4 percentage point increase). The costs are 2 percentage points lower if we use the median salary for the nation ($46,280). This suggests that our main calculations are reasonable, but that actual ORD cost will depend on the salary calculations.

Table B1: Simulated and reported 101 allocations (FY02)

	101 Allocations	Group	Percent change	Continuous model	Percent change	Continuous with Step	Percent change
Original calculation (see Table 7)							
Small (n=17)	$1,017,461	$2,852,187	280%	$2,385,091	234%	$2,630,646	259%
Medium (n=39)	$12,703,357	$15,905,353	125%	$16,554,210	130%	$16,432,387	129%
Large (n=11)	$7,724,722	$9,434,006	122%	$10,030,134	130%	$9,748,470	126%
Total	$21,445,540	$28,191,546	131%	$28,969,435	135%	$28,811,503	134%
Salary capped at $80,000							
Small (n=17)	$1,017,461	$2,855,142	281%	$2,475,253	243%	$2,641,786	260%
Medium (n=39)	$12,703,357	$16,370,706	129%	$17,494,062	138%	$16,979,237	134%
Large (n=11)	$7,724,722	$9,639,950	125%	$9,899,630	128%	$9,973,275	129%
Total	$21,445,540	$28,865,798	135%	$29,868,945	139%	$29,594,298	138%
Salary set at national average ($46,280)							
Small (n=17)	$1,017,461	$2,809,449	276%	$2,422,836	238%	$2,584,816	254%
Medium (n=39)	$12,703,357	$15,719,435	124%	$16,569,029	130%	$16,184,905	127%
Large (n=11)	$7,724,722	$9,324,716	121%	$9,634,961	125%	$9,602,565	124%
Total	$21,445,540	$27,853,600	130%	$28,626,826	133%	$28,372,286	132%

Note: Only includes VAHCS that reported 101 allocations for FY02
*101 allocations as reported by the AO.

APPENDIX C: DATA REQUIREMENTS

Data Requirement

The proposed allocation model is easy to calculate and has few data requirements. To calculate the allocation, ORD will need to collect the following information from each research office:

1) The number of VA funded projects in prior fiscal year.
2) Whether the site has an Institutional Review Board for human subjects or uses the affiliate's IRB.
3) Whether the site has an Institutional Animal Care and Use Committee or uses the affiliate's IACUC.
4) The number of committee and subcommittee "actions" in the prior fiscal year. An action is a new initial review, an annual renewal, or an amendment. Actions are based on the following 5 committees:
   a. Research safety
   b. Biohazards, *if present*
   c. Institutional Review Board (human subjects), *if present and not through affiliate*
   d. Institutional Animal Care and Use Committee, *if present and not through affiliate*

Updating the allocation model

It is recommended that ORD collect additional data from each site to annually update and periodically evaluate the allocation model. This could be collected via the Promise system, Austin Automation Center, VAHCS human resource departments, or via another reporting mechanism.

1) Collect the FTE, title and source of salary support (101 core, 101 flexible, 105, medical research, nonprofit, or affiliate) for each research office staff member.
2) Number of initial reviews, annual renewals, and amendments for
   a. R&D
   b. Research Safety
   c. Biohazards
   d. IRB
   e. IACUC
3) Whether the affiliate handles the
   a. IRB
   b. IACUC
4) Expenditures for
   a. Supplies
   b. Education/ training
   c. Other (specified)