User Perspectives of the eRA System

A Survey of Extramural Staff

Conducted as a part of the eRA Needs Assessment project by the Office of Extramural Research

OPASI Evaluation Project 04-2007-OD-OER

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1   Executive Summary

A survey was conducted in June of 2008 of approximately 4,000 NIH extramural staff in order to provide input to an evaluation project entitled "Needs assessment for the replacement or refurbishment of the eRA system".

The survey produced the following results:

- Overall satisfaction with the eRA system is generally high with 39% "Satisfied" or "Very Satisfied" and an additional 36% "Neutral"
    - There was some anecdotal evidence that negative perceptions of the eRA system were perhaps driven by other factors such as a poor understanding of the eRA governance process or experiences of eRA from several years ago.
    - Satisfaction was very high for the QVR and ECB modules but the satisfaction results may be biased by the highly positive view of the responsiveness of the respective development teams
    - Satisfaction was high for the Internet Assisted Review module for its positive business impact and ongoing change designed to meet users' needs.

- While the number of respondents was insufficient to draw clear conclusions, responses indicated a perception of some issues with eRA that warrant further investigation, specifically:
    - The consistency of data held in eRA has shown major improvement since 2005 when users noted this as a critical issue
    - Respondents reported high levels of satisfaction with the reliability of the eRA systems, a reflection of the strong improvements made by the eRA program over the last four years in program management, requirements processes and testing
    - Further investigation of performance of the Program and Receipt and Referral Modules is warranted
        - It should be noted that in some cases, the lack of satisfaction in performance is due to changing needs due to evolving business practices rather than issues with the systems as designed.
    - There were some indicators of dissatisfaction with the functionality provided by the Population Tracking and Committee Management modules. These should be investigated further to ascertain the root of the issues
    - Several issues were noted that are rooted not in design flaws within the eRA system, but are caused by failure to systematically re-engineer IT systems in response to changes in extramural business process, policy and practice

- The survey identified gaps in functionality provided by the eRA system, often supported by IC extension systems or small locally developed databases or spreadsheets.
    - Budget tracking from planning through closeout was noted by many respondents and this is being addressed by the eRA program through the implementation of the Electronic Tracking and Analysis module (eTA)
    - Integrated tracking and management of contracts and grants
    - Support for notes that do not form part of the official grant folder

- o Support for communication and collaboration tools with tracking of communications with the grant
  - o Integration of data sources into eRA searches including PubMed, NIH, DHHS, agency, professional or advocacy organization websites
  - o Support for some review activities such as candidate lists, conflict tracking and workload management
  - o Protocol Management
  - o Scientific Progress Tracking
- Respondents indicated a clear need for changes to business processes with accompanying changes to IT systems in order to support the NIH's goals of increased clinical, translational and multi-disciplinary research
  - o Based on these comments, the authors and the eRA program managers believe that a strong focus on the integration of business process modeling with IT system planning will be a key factor in the success of future extramural system development
  - o The survey has provided a list of NIH staff with the knowledge and motivation to assist further efforts to determine the future of extramural systems including the business process modeling noted above
  - o There is also a clear need for cohesive business and IT governance if the evolution of extramural systems is to successfully continue to meet the needs of the NIH
- Although formally out of the scope of this project, some of the problems identified by the survey (outdated opinions regarding data quality, unrealistic performance expectations, feature creep) do indicate a need for a strong outreach/communications effort on the part of the eRA Program. More importantly for the question of change in eRA systems, they indicate that change is intrinsic to eRA systems and that business governance and IT governance must better synchronize their priorities and funding support.

2 Introduction

As a part of an evaluation project entitled "A Needs assessment for replacement or refurbishment of the eRA system" a survey was conducted to gather the views of users of the eRA system. The following document summarizes the results of the survey and suggests some conclusions that may be drawn from the results.

2.1 Project Goals and Scope

As stated in the proposal for the evaluation project:

> "The purpose of the proposed evaluation is to assess the need for replacement or refurbishment of the eRA system by identifying the nature and extent of the current problems with the eRA system.. It is designed to assess the needs of stakeholders, and then to derive the appropriate development goals for the eRA program, and how the program should be modified in order to achieve those goals. These modifications may include changes to both the technical and human aspects of the program. Any assessment of the need for replacement or refurbishment of the eRA system must be systematic, solid and convincing to all stakeholders."

The evaluation proposal identified several business goals for the NIH extramural program that derived from work performed by the Office of the Chief Information Officer (OCIO). It was determined that meeting these business goals would result in the need for significant changes to extramural business processes and the systems that support them, particularly the eRA system. The goals are summarized in Table 1 below.

Table 1. OCIO Identified Extramural Business Goals

Goals
Get more money into the hands of investigators faster
Reduce cycle time from receipt to notification of award
Provide electronic receipt and processing of grants
Support multiple PIs on one grant including PIs at different locations
Support "tethered applications" and "linked awards" to allow greater flexibility for collaborative research
Support grants funding shared with other agencies
Support early identification of multi-disciplinary research
Support management of trans-NIH and trans-agency research
Flexible research administration processes and funding approaches
Support optimization of research administration business processes through high flexibility and extensibility of the eRA system
Support more innovative approaches to evaluation of the scientific merit of applications
Aggregation and flexible categorization of information for reporting purposes including enterprise wide reporting of the whole extramural research portfolio – grants, contracts and cooperative agreements, across multiple ICs and multiple funding agencies, and integration of reporting across extramural and intramural programs
Adoption of technology that can support more efficient and flexible extramural research administration
Support more rapid changes in Grants Management requirements (changes are currently outpacing

Goals
the ability of the program to respond)
Support external users (PIs and others) as core stakeholders of NIH grant systems
Utilize the investments made by ICs in grants management extension systems throughout NIH
Support sharing of best practices developed by ICs across NIH

The evaluation methodology included a survey of extramural systems users designed to:

- Identify levels of satisfaction with the eRA system

- Identify perceived issues with the eRA system

- Assess potential needs for changes to the eRA system

- Assess the need for changes to business processes and potentially policy

- Identify gaps in coverage provided by the eRA system including IC extension systems and other small-scale software systems

- Provide input to speculative future plans for extramural research funding and management systems

- Identify staff with the motivation, interest and knowledge required to develop future business processes

2.2   Scope

The survey is focused on the systems that comprise the Electronic Research Administration systems (eRA) developed, maintained and supported by the Office of Research Information Systems (ORIS) within the Office of Extramural Research (OER). In this document the term "eRA" refers to these systems, including the modules of IMPAC II (Receipt and Referral Module, Grants Management Module etc.), the NIH Commons, iEdison and CRISP+. "eRA" is explicitly not referring to the organization that performs development, maintenance of support and as such, the conclusions drawn in this document are limited to conclusions regarding these systems and not the organization. Where comments made by survey respondents referred to the eRA program rather than the systems, these have been passed on to the eRA program.

It should be noted that in respondents' responses to requests for "additional comments", the comments were often focused on factors that are not directly attributable to either the eRA system or the eRA program but to a more fundamental aspect of how the NIH does business. For example, there were multiple comments regarding the need for aggregation of grant data at levels above an individual grant application, and the resulting award i.e. a competing segment. This report tries to distinguish between performance of the eRA system under current conditions ("deliver what was promised") and the desire for new functions.

3   Methodology

3.1   Survey Structure

The survey was structured into three major sections with the first section mandatory and the following sections optional. Within each section there was the opportunity for respondents to provide additional information if they desired.

- Section 1: Satisfaction with the eRA system

- Section 2: Identification of functionality gaps in the eRA system

- Section 3: Business process improvement and associated system and policy changes

In addition to the major sections above, the survey gather demographic information relevant to the survey such as the IC and work responsibilities of the respondent. Survey responses were anonymous unless the respondent wished to provide contact details to allow later follow-up.

3.2   Target Population and Mechanics

The survey was targeted at the views of all NIH extramural staff and as such the results reflect the views of this group of users of eRA and should not be construed to reflect the views of all users. In particular, the survey does not reflect the views of users of the external facing systems, that is to say users who are not NIH staff.

Approximately 4,000 invitations to participate were sent by the OER Office of Communications to extramural staff via e-mails to the OER extramural staff listserv. The same population was again invited towards the end of the survey period. The number of 4,000 is less than the total number of users of the internal eRA systems as these include users in other operating divisions of the Department of Health and Human Services (FDA, CDC, AHRQ) and other users of eRA including the Veterans' Administration. The number does however approximate the number of eRA users within the NIH and as such it is felt that the survey results are reflective of this community's views.

Invitees were provided a link to a custom website developed using the open source Lime Survey tool[1]. The website led them through the questions adjusting responses to previous responses as needed. The website set a cookie on the user's computer to avoid multiple responses from the same computer though it could not prevent a respondent who made multiple responses via different computers.

4   Results

There were a total of 471 responses to the survey (approximately 12% of those invited). Of the respondents, 48% (229), 6% of the total population) opted to provide answers to one or more of the optional sections of the survey.

Using a 90% confidence interval, the response rate above indicates that survey has an overall margin of error of +/- 4.6% for those questions addressed by all respondents. Margins were

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[1] http://www.limesurvey.org/

higher for the questions where the population was a subset of the overall population such as those targeting users of specific eRA modules. In this case the margin of error ranges from +/- 8% to +/- 22%. Those questions in the second, optional part of the survey provide only anecdotal evidence for trends and as such no statistical analysis has been performed. The results for this section are simply grouped in to "themes" of response and reported.

Where analysis was performed, results were determined to indicate a significant trend where the raw result percentage reduced by the margin of error was greater than 50%. For example, if 80% of users of a specific module reported a particular response and the margin of error for this question was +/- 16%, this would result in a low end response range estimate of 64. Since the low end of this range (64%) is greater than 50%, this would be deemed to be a significant trend and as such should be the target of closer examination to determine causes.

4.1   Respondent Demographics

Approximately 88% of the respondents had 3 or more years of experience with eRA, with 62% having greater than 5 years. it also suggests that the results may be skewed towards reflecting a view of the eRA system of several years ago rather than the current state of the system. Evidence for such a possibility can be drawn from comments made by respondents in the survey where their comment reflected an issue that was known, and had been resolved at some time in the past.
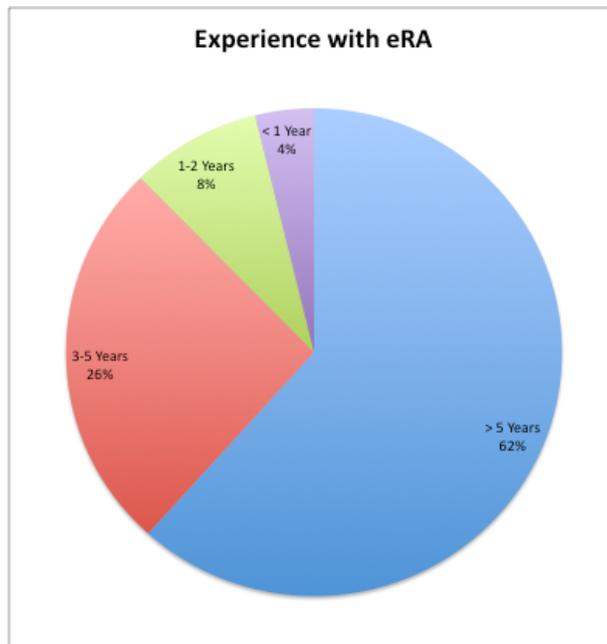

Figure 1. Survey respondents' years of experience with eRA

Respondents strongly tended to be regular users of eRA with 89% using eRA systems at least a few times a week, with 70% using eRA in some form every day.
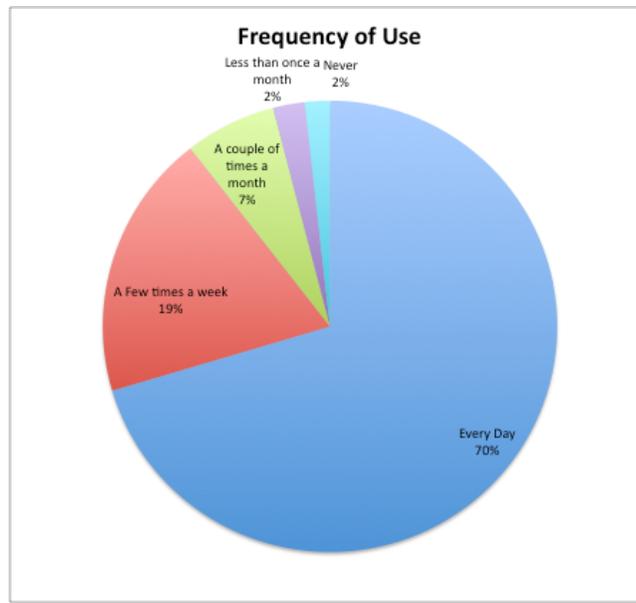
Frequency of Use

Figure 2. Survey respondents' frequency of eRA use

Examination of the numbers respondents by business process area and funding type participation indicated a broad coverage of the extramural business of the NIH and are believed to be broadly reflective of the staff profile of the NIH.

Respondents by Business Process Area

Figure 3 - Respondents' participation in the business process
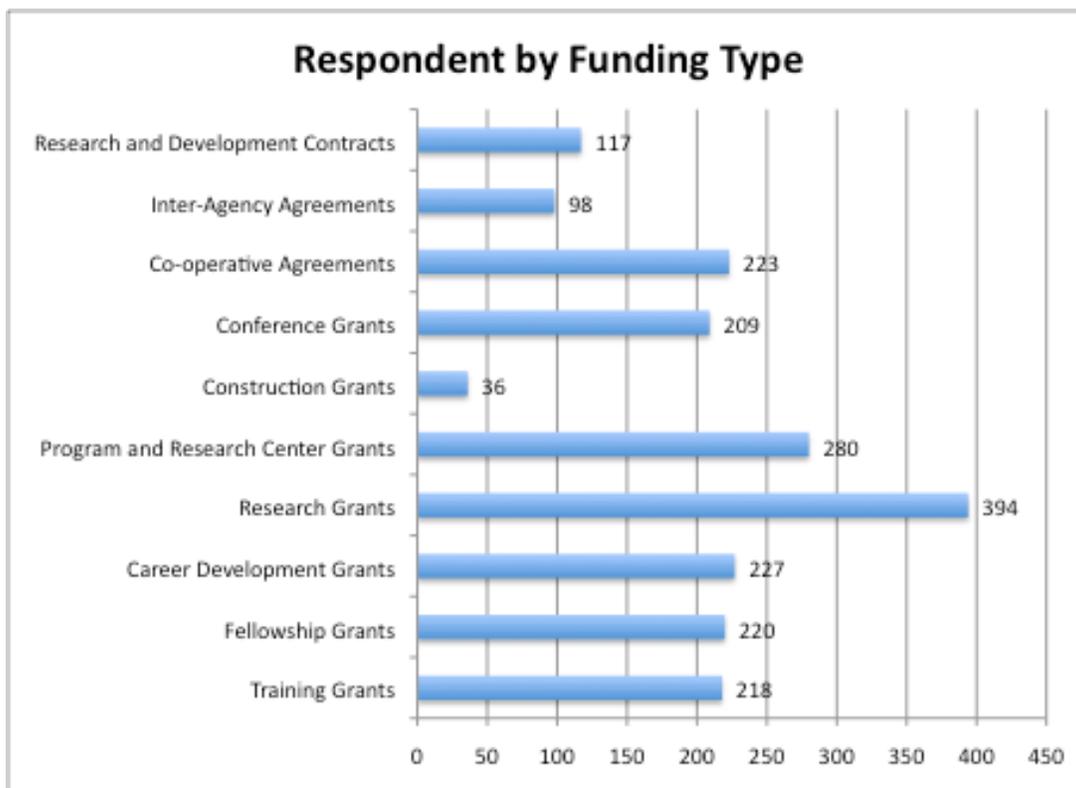
Respondent by Funding Type

Figure 4. Survey respondents' participation by funding types managed

4.2   Satisfaction with the eRA System

Survey respondents were asked for their opinions on their level of satisfaction with the eRA system. Each topic was posed as a question and the respondent asked to respond on a scale from "Extremely Satisfied" to "Neutral" to "Extremely Dissatisfied", e.g. "With respect to the eRA/IMPAC II system overall, please indicate your level of satisfaction with the data consistency of the system".

In addition, respondents were asked their opinions on the specific modules they used in their day-to-day activities. The results of these individual responses have been averaged to determine an overall satisfaction score. It was felt that this measure of satisfaction, where the respondents had taken the time to consider the individual modules they used, provided the truest assessment of satisfaction.

This approach was taken because the detailed module-by-module responses reveal some data that indicate that the overall assessment of the eRA system do not reflect the views of the eRA system, but instead reflect a mix of the views of the system as well as the views of the program that developed the system. The QVR module for example showed a very high level of satisfaction from respondents, with 94% indicating that they were satisfied or very satisfied. However, a review of the comments provided by respondents in association with their ratings indicate that the response may be significantly biased positively due to the perceived responsiveness of QVR to

user requests, rather than the satisfaction with the tool itself. Several respondents for example noted that they were unhappy with some technical aspect of QVR, but indicated they gave it a high satisfaction rating because of the responsiveness of the development team. Even in cases where the comments reflected some significant issues with QVR, they also contained very positive views of the development team that correlated with a higher overall satisfaction than the negative comments about the system would imply.

The opposite can be said to be true of the eRA developed systems where negative views of the program correlated with low satisfaction ratings, while specific ratings on system reliability, performance etc. were significantly higher. Exacerbating the problem is the indication from many comments that the negative responses may have derived from experience from some time in the past. For example, there were several negative comments about the process of setting priorities for development and the perception that the eRA program is making all priority decisions, something that has not been true for 4 years or more. These comments may also indicate a bias in the responses – i.e. that those who were more dissatisfied tended to respond more. For this reason, we have chosen a very conservative measure for significance of a result, and only suggest further investigation rather than to draw a conclusion.

Therefore, the data presented below are based upon the detailed rating of specific modules for performance, reliability, functionality and data consistency. We believe the data provide a balanced view of the overall perception of the eRA system, independent of the view of the eRA program.
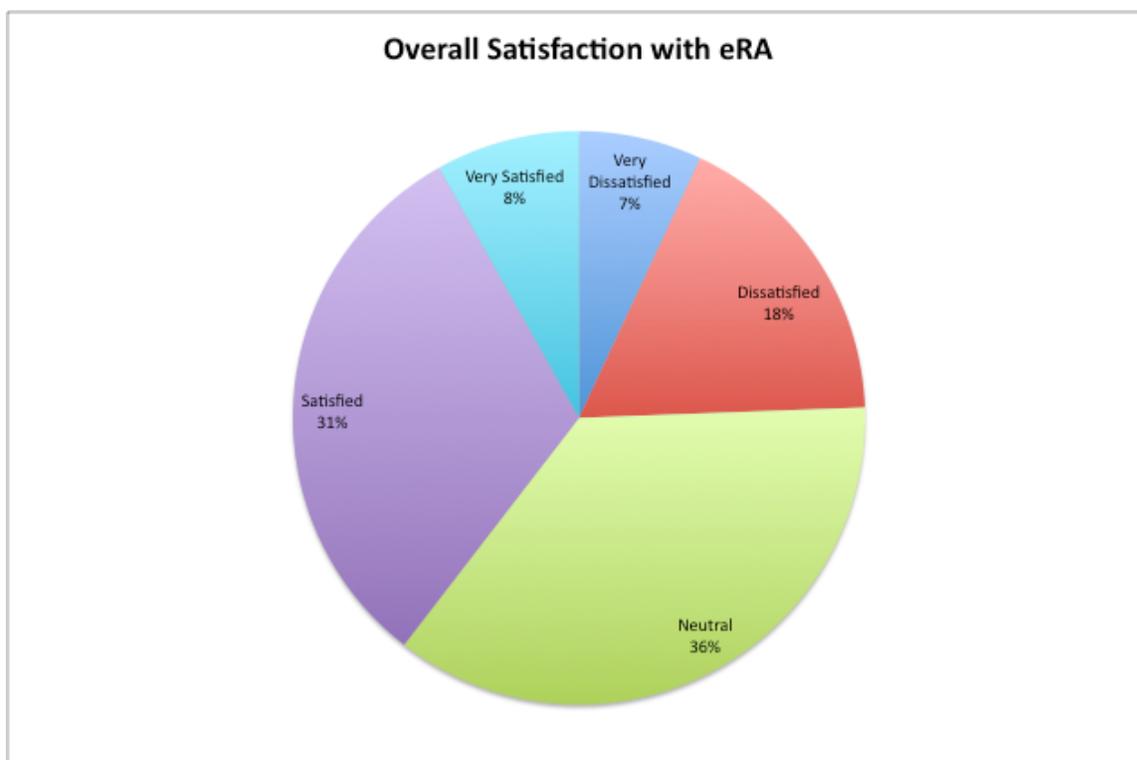

Figure 5. Overall Satisfaction with the eRA System

Looking deeper into the responses, the satisfaction with the individual modules varies greatly from module to module. The following charts represent responses to the specific questions regarding overall satisfaction with the module, the reliability of the module, performance and finally the functionality provided. Table 2 below indicates the number of users of the module in the last 12 months, the number of respondents, the percentage response and the survey margin of error based on a 90% confidence interval for those questions where the respondents represent a sub-population – that portion of the population that use a specific module.

Table 2. Response rates and margin of error for module specific questions

Module	Unique users	Respondents	% Responding	Margin of Error
GM	1,003	7	1%	+/- 24.7%
PGM	2,564	34	1%	+/- 11.2%
RR	181	8	4%	+/- 22.8%
CM	1,063	11	1%	+/- 19.7%
ICO	898	9	1%	+/- 21.8%
POP	659	8	2%	+/- 23.1%
Review	1,108	25	3%	+/- 13.0%
Crisp+	426	12	1%	+/- 18.8%
TA	443	3	1%	+/- 37.9%
QVR	4,045	34	1%	+/- 11.2%

Therefore, the data presented below are based upon the detailed rating of specific modules for performance, reliability, functionality and data consistency. We believe the data provide a balanced view of the overall perception of the eRA system, independent of the view of the eRA program.

The charts below reflect the results of the satisfaction questions relating to overall satisfaction, satisfaction with reliability, performance and the functionality provided by each module. For each satisfaction factor two charts are presented: The first shows the split between satisfied and non-satisfied users with the margin of error indicated in each bar. For this chart a satisfied user responded that they were Very Satisfied, Satisfied or Neutral while dissatisfied users responded that they were Dissatisfied or Very Dissatisfied with the module. As noted above, where the lower range of the error bars on the dissatisfied users is above 50%, the result is regarded as significant and warrants further investigation. The second chart reflects the same data but is formatted with to show the split between satisfied and dissatisfied users by module. It should be noted that not all satisfied/dissatisfied percentages total 100%. In these cases one or more respondents answered the question with either "Not Applicable" or "Don't Know".
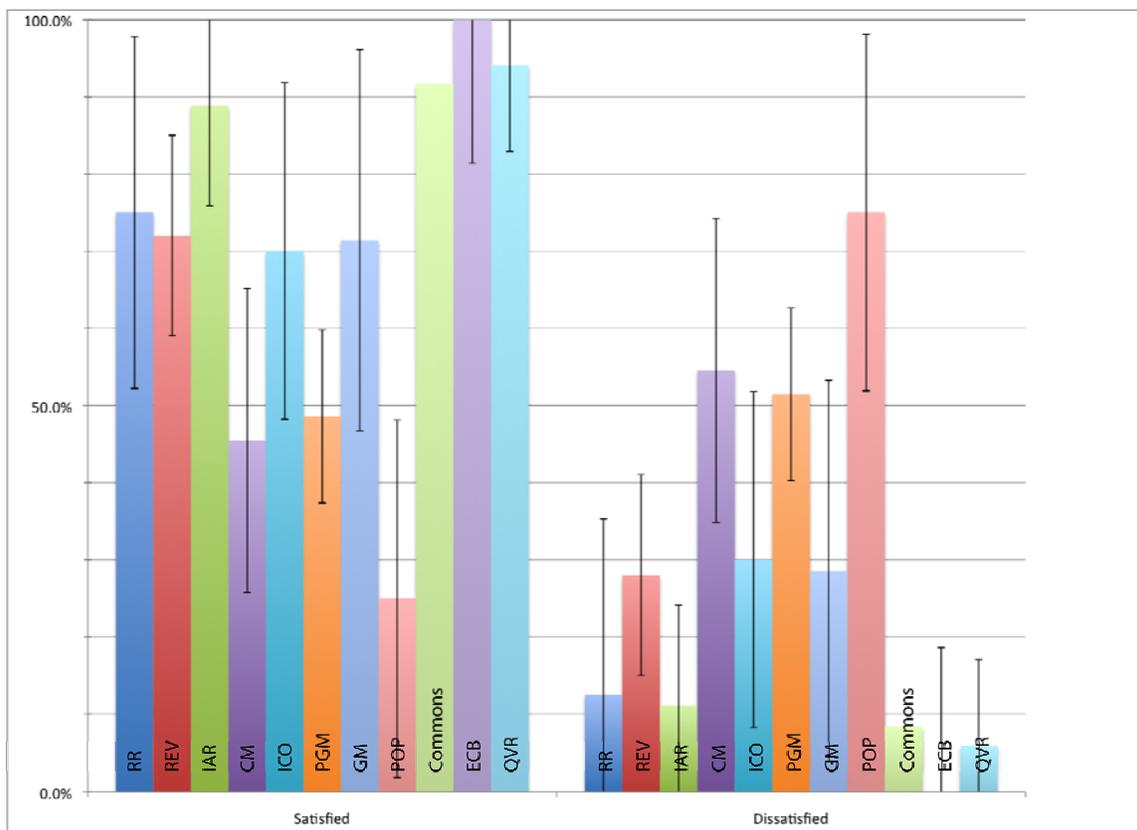
Figure 6. Overall satisfaction with eRA modules

Figure 6 above indicates a significant level of satisfaction with most eRA modules with the highest satisfaction reported for QVR and ECB modules. Based on the comments associated with these modules much of the satisfaction appears to be derived from the development process and technologies used by the QVR and ECB teams and the resulting ability to rapidly make changes to these modules. This does not necessarily mean however that eRA should adopt the same processes and technologies as both QVR and ECB are relatively low risk systems. QVR in particular, as a reporting system that does not modify data does not pose a significant risk since a defect in the application would not result in data loss and so a lower level of rigor in the development process is appropriate. A similar case can be made for the lower risk of ECB given the relatively small number of users and the fact that it does not modify core eRA data. The mission critical nature of the rest of the eRA modules require a significantly higher level of rigor in the development and testing process resulting in longer development cycles. The comments made by respondents make it clear that this perspective is not well understood by users.

It was noted by several respondents that the high level of satisfaction with the IAR module was only partially associated with the effectiveness of the module itself. In fact,

respondents noted several issues that would generally cause them to have lower satisfaction. Statements that their high level of satisfaction was due to the continued improvement observed in IAR often countered the negative comments. This statement again suggests that satisfaction is derived from system behavior and performance as well as programmatic factors.

Also clear from the chart above is that there are significant satisfaction issues with the Population Tracking Module and near significant issues with the Program and Committee Management Modules.
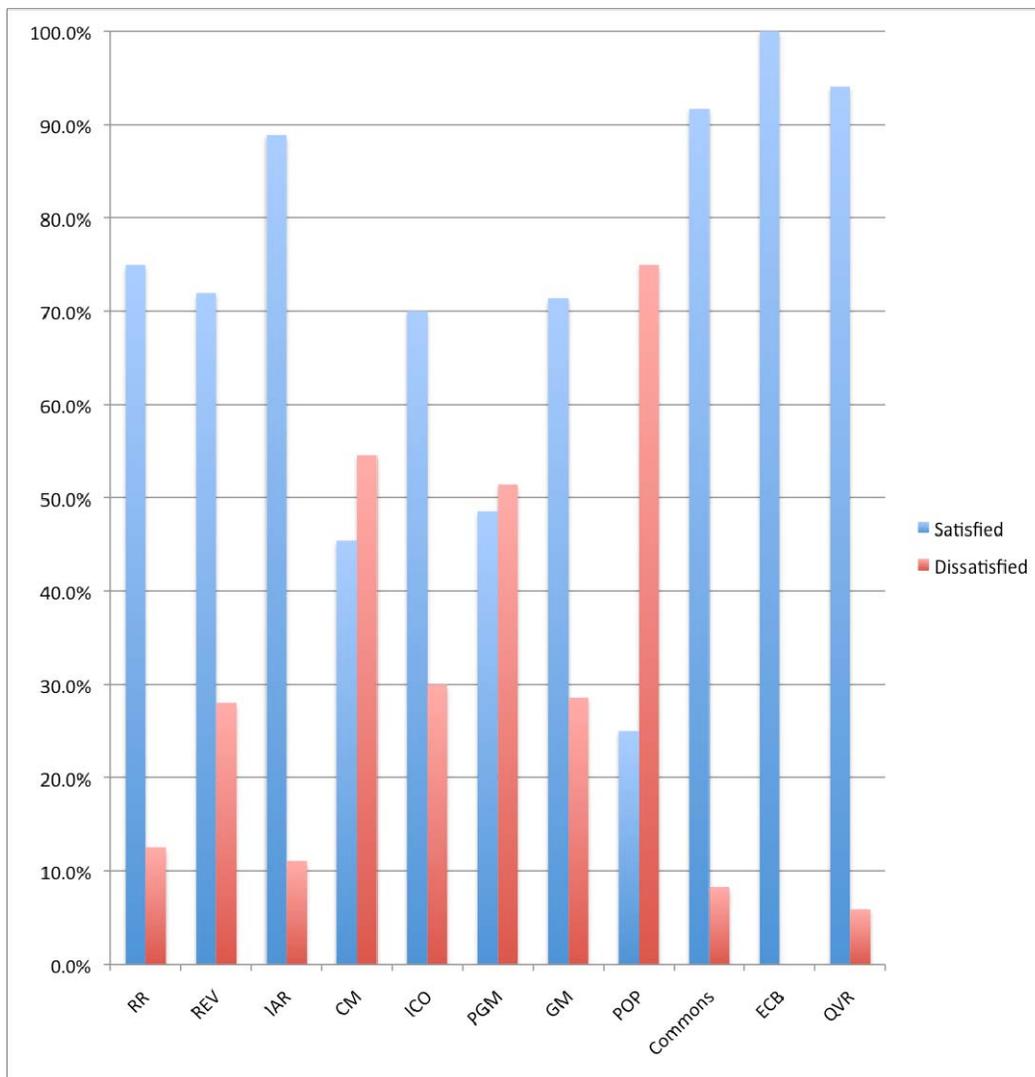

Figure 7. Overall Satisfaction/Dissatisfaction by eRA module

User Perspectives of the eRA
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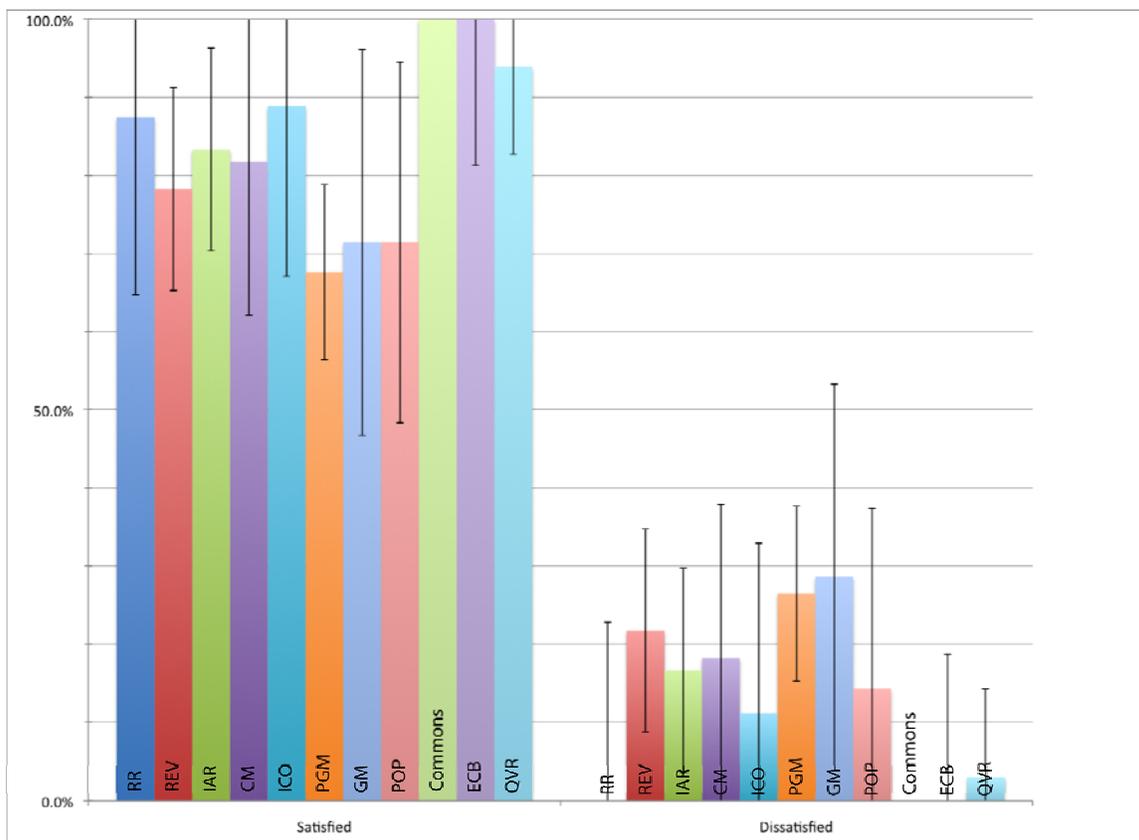Research oer@od.nih.gov

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Figure 8. Satisfaction with eRA module reliability

Figure 8 above indicates that there is significant evidence for satisfaction with the reliability of all eRA modules. Anecdotal evidence from the comments made in the survey indicates that this is a change in viewpoint from the past where reliability was perceived as a significant issue. This is likely due to a combination of the completion of the migration to J2EE with resolution of initial reliability issues along with the advances the eRA program has made over the last five years in the implementation stronger program management, requirements management and testing practices – all of which typically correlate with improved reliability of systems.
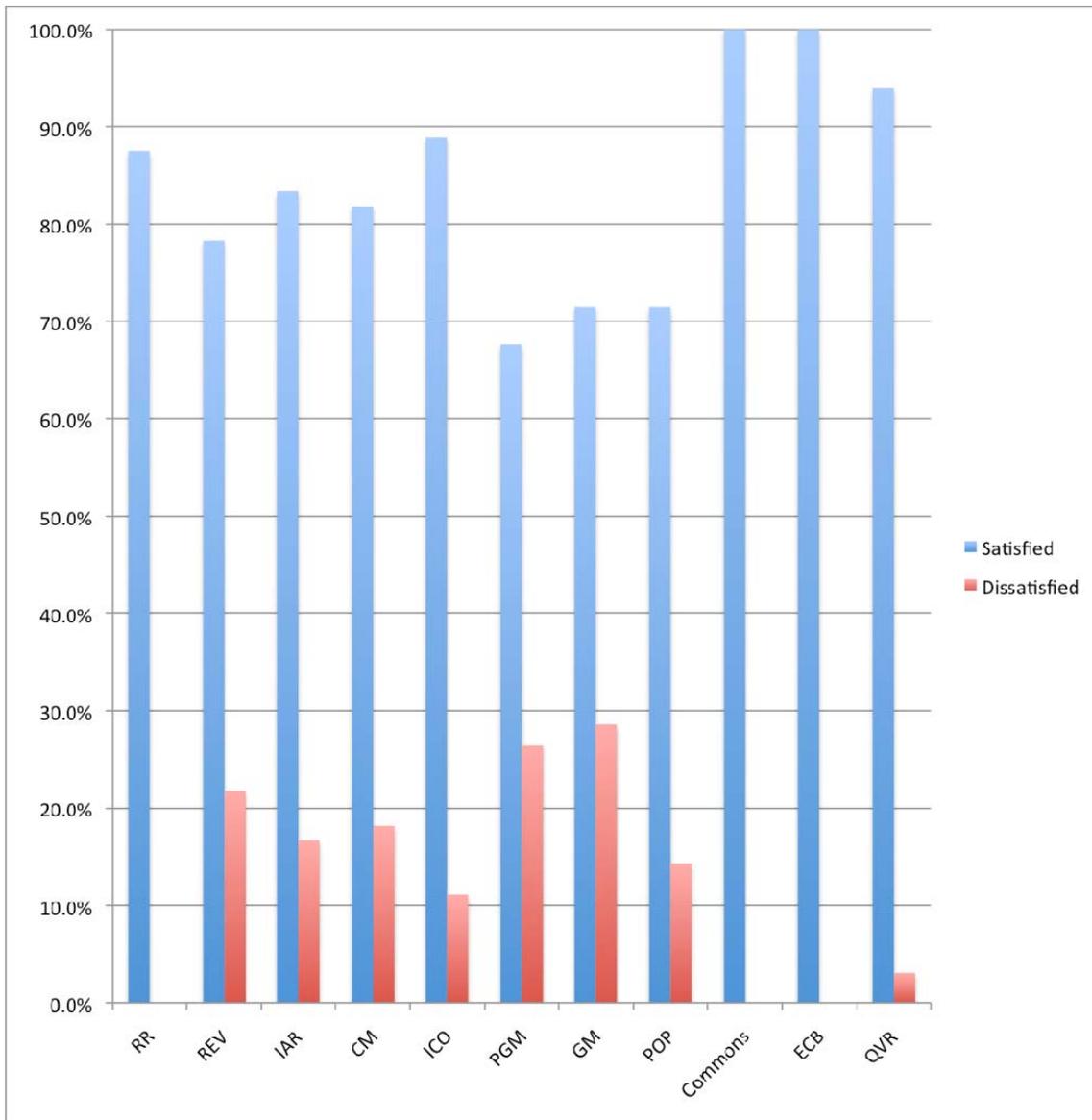
Figure 9. eRA satisfaction with reliability by module

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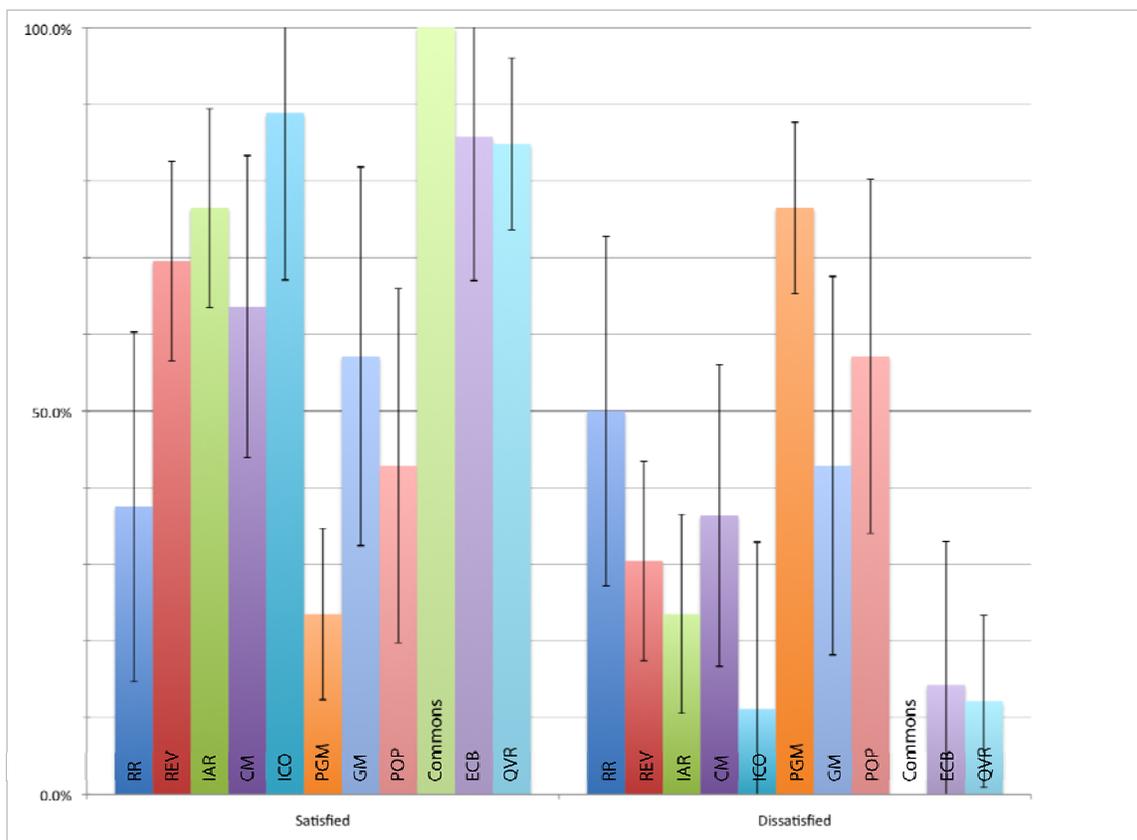Research oer@od.nih.gov

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Figure 10. Satisfaction with performance of eRA modules

The questions relating to performance provide evidence that much of the root of dissatisfaction with eRA modules results from perceived performance issues. Figure 10 above indicates significant evidence that users perceive the Program Module to have performance issues. This is backed up by the strength of the comments made regarding performance of the program module by users. While not significant by the standards noted above, the fact that 50% or more of respondents indicated performance concerns with the Receipt and Referral and Population Tracking modules suggests that further investigation of the performance of these modules is also warranted.

At this point it is worth noting that while some users report a perception of performance issues, where performance requirements are stated for eRA modules, those requirements are met 99% of the time. It has been suggested that the reasons for the perception of poor performance lies in part with the change in users' views on what is acceptable performance. Essentially, the performance of eRA modules may not have kept pace with the expectations of users.

In addition to changes in user expectations, the eRA system has undergone major stress factors that may have resulted in reduced performance, particularly at peak usage times

such immediately following receipt dates, prior to and immediately following Council meetings and at the end of each financial year. These additional stresses have resulted from a tremendous increase in load that primarily resulted from the electronic receipt of grant applications and the "downstream processing" required to manage these applications. Today there are typically over 20,000 logons to Commons each day; four years ago there were fewer than 1,000 logons/day. Even though eRA is only now replacing its servers and increasing capacity, it managed to provide reasonable performance over the past four years by improving the efficiency of its applications.

Even where performance has not been impacted by the increased load, perceptions of performance issues may increase as individual workloads increase – where an individual staff member has to deal with more applications, wait times for system responses become more important and where a user may have been able to complete a days work with ease with a certain level of performance, the increased workload may leave them pressed for time.
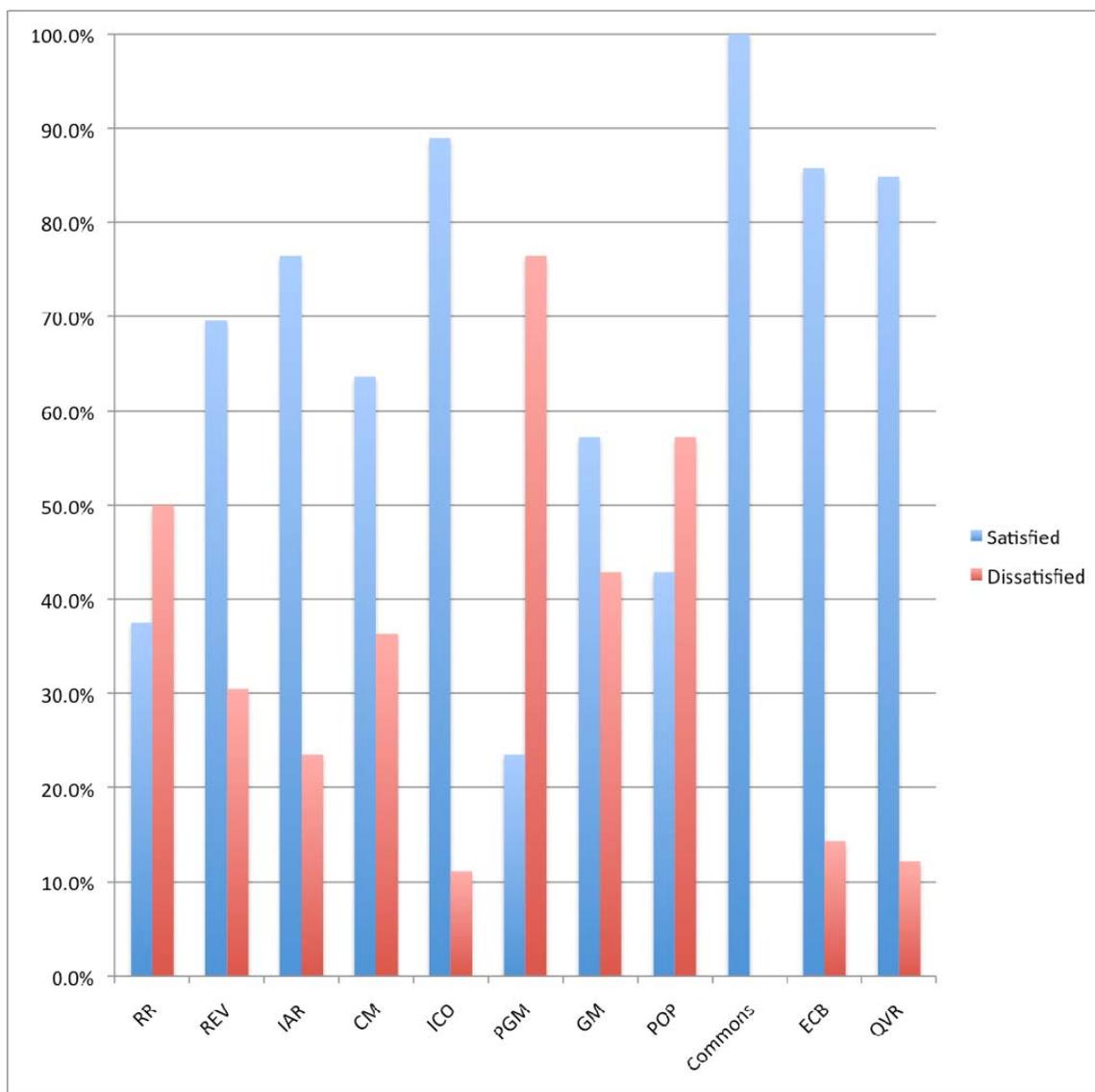
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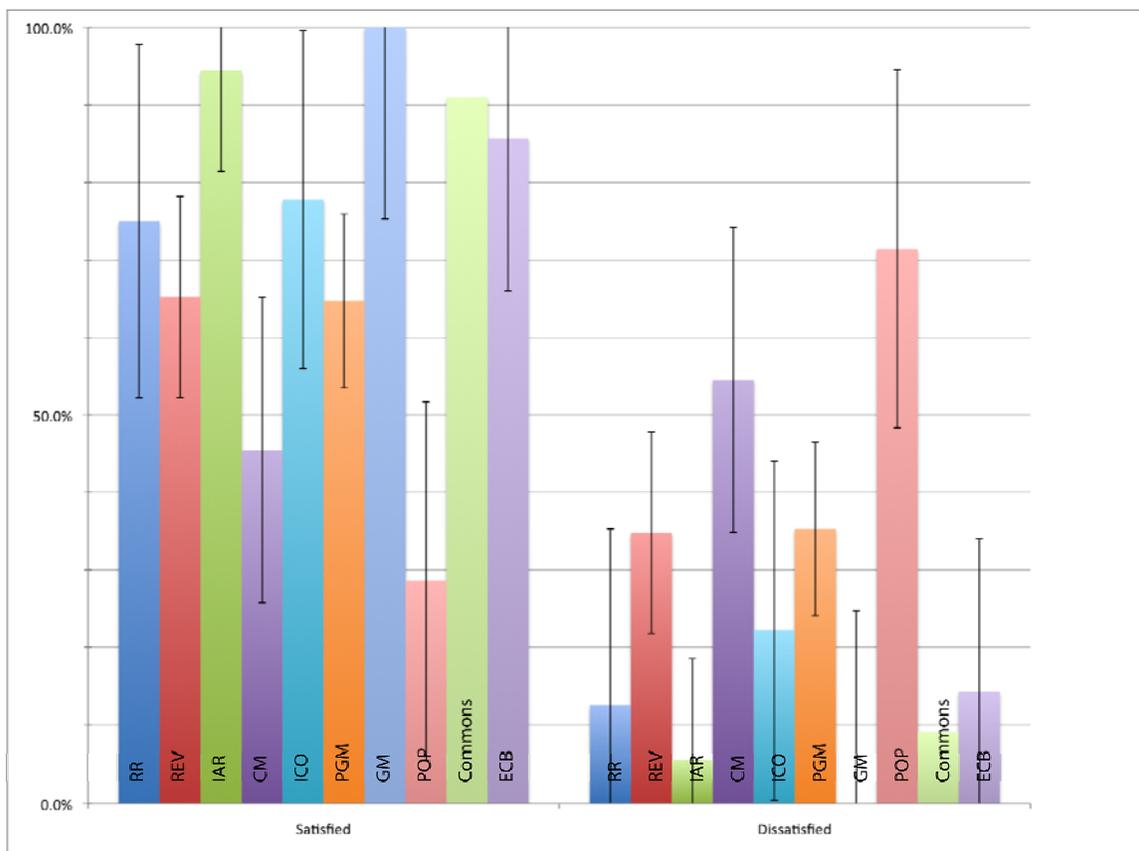**Figure 11. eRA satisfaction with performance by module**

Figure 12. Satisfaction with provided functionality

In terms of the functionality provided by eRA modules, it is apparent that in most cases the modules provide the core functionality required by the user. The exceptions as indicated by Figure 12 above are the Population Tracking module with a near significance dissatisfaction level and Committee Management where a trend is suggested that should be investigated.

The comments from respondents associated with the functionality questions suggest that while there is high satisfaction with the functionality provided, there are significant gaps in coverage in some areas and a lack of integration between eRA modules and between the eRA modules and other systems. Of particular emphasis in the respondent comments was the need for a single sign on system that was fully integrated with the NIH Login.

Some of the respondent comments regarding the functionality of the Program module imply a disconnect between the requirements the module implements and the needs of the program community. In particular program officials strongly expressed the need for integration between portfolio analysis and visualization tools and the program module. This kind of tool has not previously been provided by eRA but has instead been developed by individual ICs and the Office of Portfolio Analysis and Strategic Initiatives

(OPASI). This implies that some consideration should be given to supporting integration of these kinds of tools with the Program module.
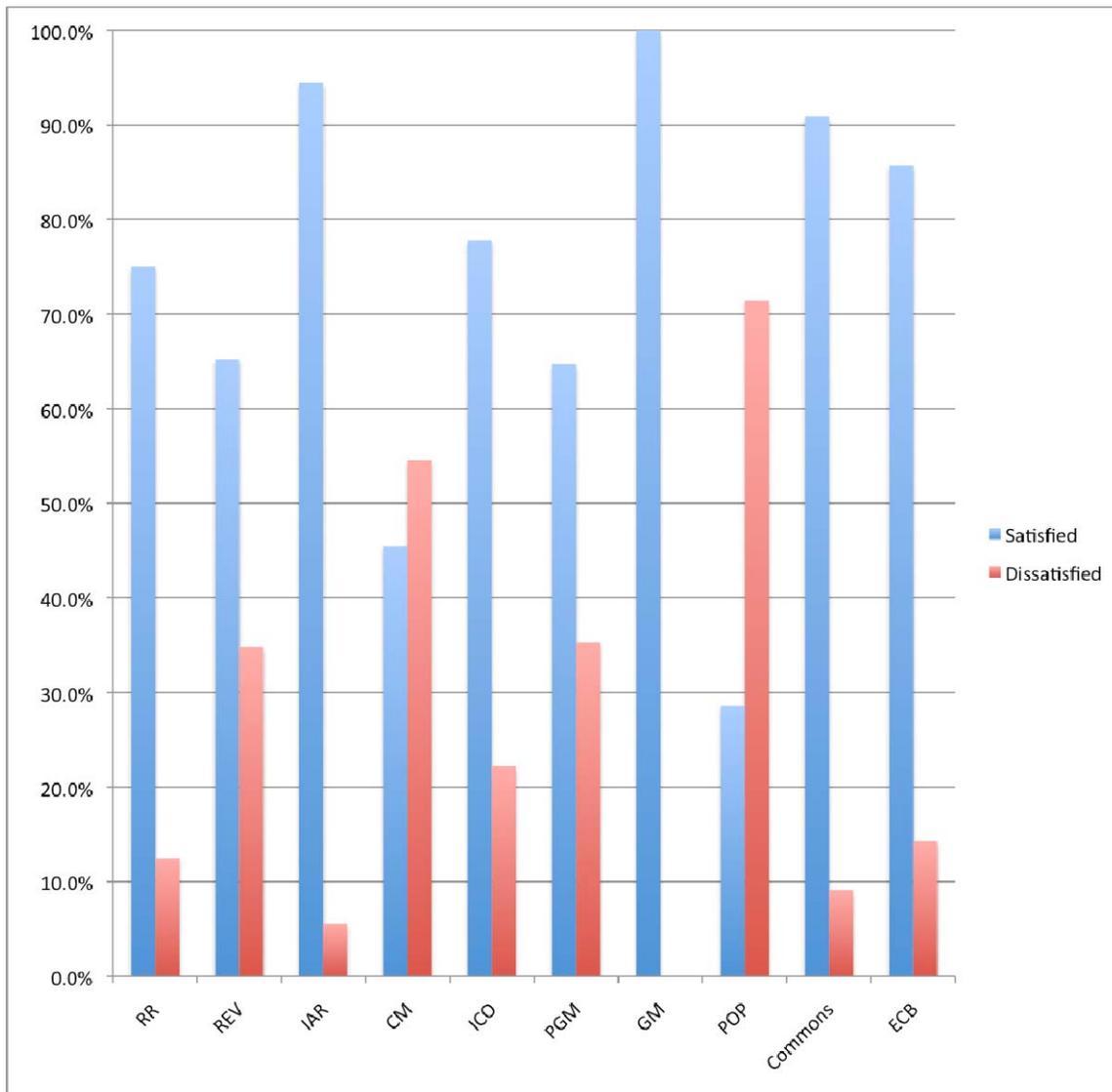

Figure 13. eRA satisfaction with provided functionality by module

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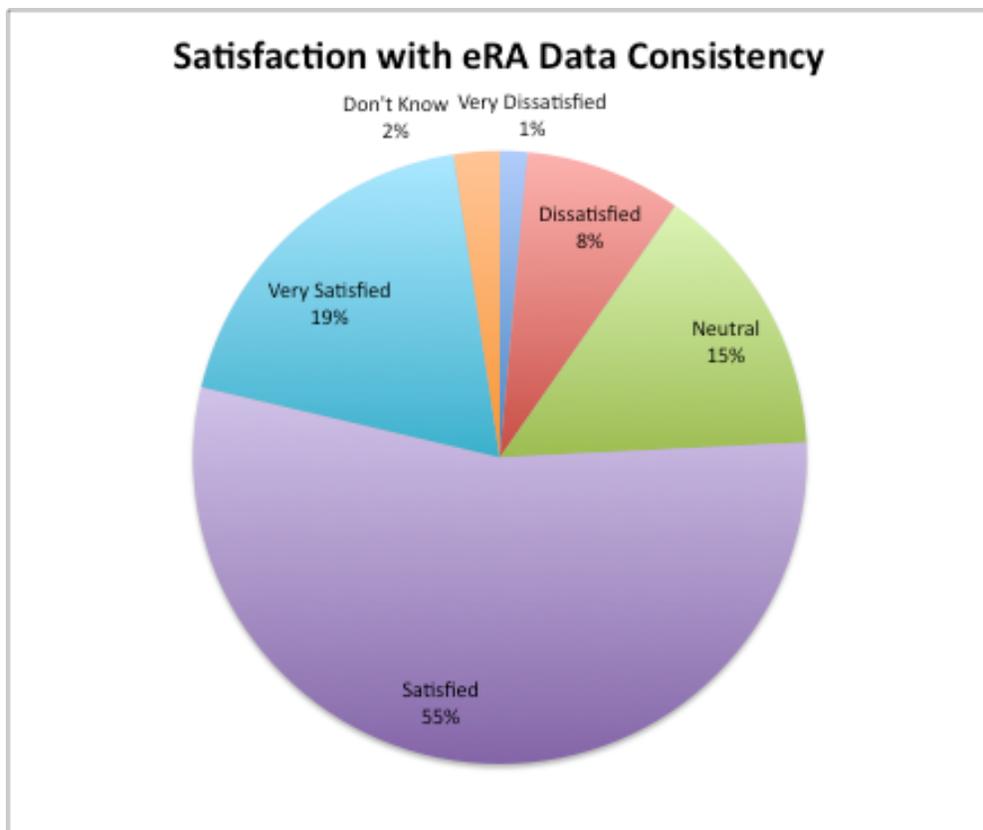Page 20

Satisfaction with eRA Data Consistency

Figure 14. Satisfaction with data consistency

Over the last several years there have been constant concerns regarding the consistency of data stored within eRA, particularly relating to duplicate profiles for applicants. During a retreat held in August of 2004 the top issue for stakeholders related to data consistency. The chart above indicates that there has been major progress made in the last four years to resolving this issue. Respondent comments explicitly noted this improvement though there were reports of data inconsistency between modules – particularly data viewed in core eRA modules and other systems including QVR.

4.3 Gaps in Functionality

The final section of the survey sought to identify gaps in the functionality provided by the eRA system. The following table summarizes common themes of gaps that were reported by users.

Table 3. Summary of Gaps in eRA Functionality

Functionality	Notes
Budget Tracking from planning through award	Includes tracking of future obligations, program discretionary funds, program budgets, etc, budget cut management, paylists, cooperative agreement pay plan. All currently handled ad hoc using spreadsheets. This will be supported through a new tracking application currently planned by eRA
Referral tracking within ICs	Currently either handled via IC built systems or spreadsheets
Contracts tracking and management	While some contracts data exists within eRA via the DCIS system, there is no support for tracking or monitoring contracts, particularly contracts that are part of a larger program of research that includes both grants and contracts – something that is particularly relevant to clinical research
Notes	There is inconsistent support for general recording of notes within eRA i.e. notes relating to a grant but that do not form part of the official Grant Folder. Where notes are stored, they are frequently only available in the module in which they were entered e.g. referral notes made in the RR module do not flow through to the REV module.
Communication and Collaboration	68 (39%) of the respondents completing the optional follow-up questions regularly cut and paste information from eRA into communications and collaboration tools e.g. Sharepoint and vice-versa. Such communication is currently ad hoc and is not managed in a cohesive or consistent manner with little if any of the communication captured in eRA.
Integration of Data Sources	Across responses to several of the follow-up questions, a common theme these Respondents observed was a growing need to integrate the results of searches in eRA with other searches in other tools. Usage varies greatly but many respondents reported using Google to aggregate data from multiple sources including internal and external resources such as PubMed, NIH, DHHS, agency, professional organization and advocacy websites and publications. There was a strong desire expressed to integrate this kind of functionality throughout NIH systems. Such a model requires careful consideration at the enterprise level and requires an infrastructure to support integration of disparate data sources.
Review activities	Reviewer candidate lists, reviewer conflict tracking and SRO workload management are currently handled outside of eRA using small databases and spreadsheets
Protocol Management	Currently managed by IC extension systems or manually using spreadsheets. With the growth of clinical research at NIH this need becomes more significant.
Scientific Progress Tracking	Tracking of science beyond that provided by the annual progress report including additional tracking required for program and research center grants and tracking for research projects that combine multiple grants and/or contracts

4.4 Coverage of the Business Process

It is evident that the current eRA system supports the basic grant lifecycle including receipt and referral of applications, peer review, partial support for Council, award, partial support for post-award management and closeout. However there are significant gaps on integration of grants management and budget.

Support for council is largely provided via the Electronic Council Book (ECB) application though respondents indicated that it does not support some aspects of Council operations in some ICs and some ICs choose to use their own systems. This may in part be due to the dual role of Council as the second level review for grant applications that is largely consistent across ICs, while the strategic role of the Council that varies more.

While the basic tasks of post award management are covered including progress reporting and supplements there is very limited support for other change requests such as a change of PI or research institution. These are handled via IC extension systems or using manual tools and changes may not always be carried into the eRA data store.

As noted in section 2.2 above, while not attributable to eRA, one of the major areas of difficulty for eRA extramural systems is founded in the fact that the central data entity to all eRA activities is the "Application". It is so central that other data entities such as progress reports and some kinds of supplements have been forced into the "Application" paradigm. Respondents noted that this model does not reflect the broader views of a Grant as a long term research project aimed at fulfilling a research goal and which may require multiple grant applications, awards, contracts, cooperative or interagency agreements. Again, this is not a design flaw in eRA, rather it reflects the needs of the system when it was being designed (and of IMPAC I before it), that it was fundamentally designed as a grant application tracking system. The business needs have evolved faster than the systems due to multiple external factors including funding constraints, unfunded mandates and differing views on business priorities.

Gaps in coverage are exacerbated by the separation of eRA modules by "business areas" based on the grant lifecycle. This may require a user to access multiple modules for a particular role depending on where in the lifecycle a grant application is currently located. This requires frequent cut and paste between modules, separate tracking in spreadsheets, databases or IC extension systems with multiple logins resulting in a system that is prone to errors and data inconsistency. From the comments made by respondents, some means of integrating the eRA modules with other systems into a single consistent user interface will be essential to allowing the NIH to meet its evolving mission objectives.

On the other hand, business areas were designed to be largely autonomous and the design of the eRA modules reflects this. As the NIH extramural activities have evolved and the business needs have changed, the mapping of modules to business processes has begun to get out of sync. This is not a fault with the design of the eRA system; rather it derives from continuing business change without the inclusion of change of IT systems in the implementation of the modified processes. The authors, and eRA program management believe that in order to ensure that IT considerations are included in the process of business change, the use of business process modeling with the inclusion of the representatives from IT organizations could be useful. However, to fully resolve the

problem it would be necessary for business changes to be made only with a full understanding of the IT implications and a commitment to funding the needed changes.

Even more critical than the integration of business and IT through business process model is the need for a governance process that tightly combines business governance and IT governance so that business decisions are made only with full consideration of the IT requirements required to support the business changes. It is evident that business changes have frequently been mandated without an understanding of the full impact and cost of the changes. The eRA program is then left trying to catch up with the needed support, often without the needed funding and with unrealistic timelines. This results in a reduced ability for the eRA program to make changes to the eRA system that align with the overall strategic technology directions that will result in the flexibility and extensibility clearly desired by respondents. This in turn results in increased long-term operations and maintenance costs that could have been reduced or avoided by investment at the beginning of the process.

The difficulties resulting from these separations are particularly evident in the management of multi-IC multi-disciplinary and multi-agency research. While eRA provides some support for multi-IC projects via the primary-dual IC designations, it does not support some of the critical business process changes that will be needed in order to support this kind of research including review of an application in multiple review groups, review of progress reports by several program directors from multiple ICs and agencies, award of segments of grants from multiple ICs budgets etc. Given that this is the direction of research that is felt to provide the greatest promise for benefit to the nation's health, respondents felt that it is critical that these issues be resolved.

Once again, this is not to say that these concerns are rooted in design flaws in the eRA system. Rather it's an example of changes in business process that were not accompanied by a corresponding change in the IT support for that business, particularly a failure to allocate funding to make the required changes. For example, multi-PI was a concept that NIH wished to promote. It was recognized that multi-PI required IT changes and the changes were incorporated in the business plans and funded. Thus, multi-PI support is reasonably well integrated into the eRA system. In a similar way, as multi-IC and multi-agency projects are becoming more prevalent due to the increased focus on clinical, translational and multi-disciplinary research, the IT funding needs to be provided as a part of the overall business change project.

In the similar way, the NIH leadership has expressed the desire to support multiple separate applications all working towards a common goal or project – "clustering" of applications. However, implementation of the IT support for such a model is not a project that the eRA governance bodies have chosen to prioritize. Respondents' comments indicated that the lack of support for clustering and other multi-application models is of concern to them in meeting their business goals. The implication of the above is that a more cohesive governance model is needed that more tightly integrates business need,

policy and IT funding governance. As the NIH moves towards greater use of the Service Oriented Architecture model for system development, this need for fully integrated governance will become even more critical to business success.[2]

4.5   Research Funding Lifecycle versus Research Lifecycle

Respondents drew attention to the distinction between the lifecycle of research funding from grant application through award through closeout and the lifecycle of the research being funding. In the latter case a research idea results in the development of a potentially long-term project to explore the idea and in some cases eventually bring the research idea into and through the clinic. The current eRA system reflects a view based entirely on the research funding lifecycle and does not address the broader issues of the research lifecycle. This distinction is often confusing to users and their expectations for what eRA can do is frequently based on the research lifecycle. Data at this scope is hard to synthesize from the more granular research funding data and so users are forced to use other systems to track the broader research projects. Respondents noted again that this separation will result in difficulty in managing the increasingly complex research projects the NIH wishes to fund. Exacerbating this issue is the fact that eRA modules support a mixed model. For example the Receipt and Referral, Peer Review and Closeout module entirely focused on funding lifecycle while the IC Operations, Program and to some degree the Grants Management module are more focused on the overall research lifecycle an hence combine tools for several parts of the funding lifecycle. This is frequently confusing to users and caused difficulty with training and a lack of awareness that new or improved functionality exists. Truly cross-cutting modules such as QVR are not integrated with the other modules resulting in the need to work with the cross-cutting module, then copy and paste or in many cases, make manual notes to allow for location of the needed information in an eRA module.

Respondents observed that what is needed is a set of well integrated systems that allows them to work with the data at the level they need to from strategic planning all the way through fulfillment of the research goals of the entire project across multiple years, multiple grants, contracts etc., and increasingly across multiple agencies.

4.6   IC Extension Systems

The survey produced a list of systems developed by IC to either fill gaps in eRA functionality or to support a custom variation of business process, frequently through extension of functionality rather than replacement. As well as major IC systems such as the NIAID Review system or the AMBIS and POTS procurement systems, there exist many small scale systems ranging from custom spreadsheets with complex macros to Access and Filemaker databases to small custom desktop or web applications. Many are

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[2]*Technical Approaches to and Considerations for SOA Governance,* Gartner Inc. Document ID: G00143592

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duplicative of one another or of eRA functionality and therefore often require double entry of data resulting in inconsistency.

The types of these extensive systems can be categorized as follows:

- Functionality not provided by eRA

- Support for variations (or perceived variations) in IC business process

- Experimentation with alternative business processes

The first two types of functionality provide real business value to the ICs that use them. There is however a tendency for these systems to remain Balkanized and not be used by other ICs resulting in ICs developing essentially duplicative systems. For example the survey reported multiple "intent to pay" tracking systems integrated with other IC systems for program management or as standalone applications. Even where the value of an IC system is recognized at the enterprise level there is little chance of the system being adopted by the broader community except via re-implementation by eRA. The roots of this issue include differing technology platforms, a desire to retain local control, a lack of mechanisms to feed funding to the developer and maintainer of a system from the users of a system and the increased costs of supporting multiple customers. Where the functionality is re-implemented in eRA, the result may be that the IC that originally developed the system fails to adopt the new functionality provided by eRA whole the rest of NIH makes use of it. An example of this is the NIAID Review system. This system was identified as a valuable tool for enhancing and reducing the costs of the review process. However, the technology platform and the politics meant that eRA "reused the requirements" and implemented Internet Assisted Review (IAR). The NIAID Review system is still in use for reviews that are run by NIAID. The result has been that the NIH has essentially paid for the development of the functionality twice, and now pays for maintaining two largely similar systems.

The IAR example above provides an illustration of both the great value that can come from using ICs as "laboratories" for the development of new processes and systems, and the downside if the development is not managed to some degree at an enterprise level to allow a new system of broad value to be deployed across the NIH.

This is a difficult problem to solve given that these IC extension systems often begin their life as an idea that results in development of a spreadsheet or small database. When this is seen as successful, the IC desires to make it available more broadly and so they implement the tool using an appropriate scale of technology. When the tool is recognized as having value across the NIH, two problems arise: The technology platform is typically not suitable for enterprise level deployment, and the need to adapt to other ICs places a financial burden on the IC that originally developed the tool that is difficult to recover.

It is clear from this inventory of IC systems that there is great potential for these systems to be used throughout the NIH. But the issues above are likely to prevent their reuse and force re-implementation unless enterprise wide governance and technology standards are implemented.

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