AHC Research Support Task Force Report (RSO)

1.0 EXECUTIVE SUMMARY

1.1 Introduction

The Provost for the Academic Health Center (AHC) assembled a Research Support Service Taskforce in September, 1996. The Taskforce was charged to develop a plan to help faculty by facilitating all of the processes involved in obtaining and performing corporate sponsored research. The fundamental objective is to improve and enhance the ability of faculty to market their research and service capabilities. A collateral goal is to do this while improving and assuring compliance with all federal, state and local regulations and guidelines so that individual faculty members and the institution are protected to the greatest degree possible, and so that the institution will stand behind faculty throughout.

Corporate sponsored research is one area for significant potential growth. Overall, in U.S. and global businesses, there is increased movement to outsourcing as a more efficient, more flexible mode of doing various aspects of business. This trend provides universities with a major opportunity, but one which they can take full advantage of only by delivering value to the corporate sponsor in a timely manner. Corporate sponsors want to deal with quality, responsive organizations and most importantly ones that they can count on. The planning and design phase of the Research Support Service Taskforce was completed over the months of September - December, 1996. The Taskforce report was completed February, 1997.

1.1.1 Objective

The objective of the Research Support Service Taskforce was to examine each and every step in the current process of applying for, receiving, monitoring and reporting on industry-sponsored research. Following the ***review of current processes and structures, our charge was to recommend changes, as needed, to develop a plan to improve and enhance the ability of faculty to market their research and service capabilities; to develop a plan to aid faculty in being more competitive in attracting corporate sponsored research; and to provide improved service to both sponsors and faculty research investigators through more responsive administrative, oversight, approval, and compliance services; and assure the seamless coordination of all institutional and regulatory policies, procedures, and approvals that affect corporate sponsored research.***

1.1.2 Scope of the Review Process

The Research Support Service Taskforce met with a broad group of internal people involved in the management of corporate sponsored research. In general, these included the director and/or other designated senior person(s) of the unit such as representatives of the Institutional Review Board; Human Subjects Committee, the Department of Environmental Health and Safety, the Office of Research Technology Transfer Administration (both Sponsored Projects Administration and Patents and Technology Marketing), the General Clinical Research Center, the co-chief operating officers of the Fairview-University Medical Center, and the University Vice President for Research, as well as with the AHC Provost and his council. The Research Support Service Taskforce also met with representatives from the Department of Surgery and the Department of Medicine of the Medical School as well as leaders of a number of other clinical departments in the Medical School and leaders involved with clinical trials in other AHC schools. Individuals from outside the AHC and University also met with the Research Support Service Taskforce, including representatives of local and multinational biomedical products corporations and a local medical research foundation that actually competes with us for sponsored research.

In the interest of protecting faculty and the institution, and avoiding some of the problems of the past, the Research Support Service Taskforce also collected and reviewed regulations and policies (federal and institutional) that govern the conduct of sponsored research. Much attention was paid to the institutional committees and processes currently in place designed to assure compliance with these regulations and policies. These regulations and policies are listed in the various appendices, the objective being to have, to the degree possible, all documents, policies and procedures pertaining to sponsored research in one place. This will serve as a resource for all faculty, staff and administration in the AHC or, for that matter, elsewhere in the institution.

This executive summary contains an overview of the Research Support Service Taskforce's principal findings and recommendations. An overriding theme that was seen was that there is no premium or reward for good performance nor consequences for gaps or delays in the overall process. We saw little evidence to show "consumer satisfaction" with any of the individual processes or the overall process.

The remaining sections of this document provide a detailed review of the current performance of research compliance monitoring and research support service functions, goals to improve performance where indicated, and a rationale for any changes recommended.

1.2 Principal Findings

The Taskforce's principal findings focus on opportunities the institution could take to provide more expeditious and improved service to faculty members and research sponsors. Overall, the Taskforce found that:

- there are no time performance demands placed on any area, committee or office involved in overall internal processes of grant submission and approval
- there is much "down" time, where a grant or contract may be in a particular office or with a committee and just "sits". The "action time" in a given committee or office might be very brief, e.g., on the order of 15-30 minutes, but for all intents and purposes the grant or contract may be interred within this office or committee for 30-60 days.
- each office or committee does its work, but there is little to no regard for how this effort could be improved to make the whole process more user-friendly for faculty and sponsors.
- there has been little or no discernible effort to look at how "parallel processing" could insure or improve quality of review, and, from a time perspective, do it in a dramatically enhanced manner. Multiple internal approvals should be acted on contemporaneously.

Recommendations for change made throughout this report are based on the following specific principal findings:

1.2.1 Conflict Review Committee

The Conflict Review Committee (CRC) has greatly expanded its authority significantly beyond that detailed in Regents' policy governing research. This expansion of authority includes, among other things, the review and approval of: (1) all industry-sponsored research whether there is evidence of conflict of interest or not; (2) budgets and research agreements related to industry-sponsored research; and (3) a myriad of other issues that have nothing to do with conflict of interest. We have been unable to find any authorization for extending this purview of review. The CRC currently requires that any potential conflict of interest be eliminated before a faculty member enters into an industry-sponsored research agreement. Federal regulations, Regents' Policy on Conflict of Interest and even the FDA, allow some categories of potential or even real conflict of interest to be managed through peer review or other mechanisms. Externally, the CRC has made the AHC more difficult for industry sponsors to access. It is a focus for scorn and derision often exemplifying how difficult the university is to deal with. Internally, the CRC has substantially delayed, duplicated, and confused the research application process through the expanded authority it has assumed.

1.2.2 Principal Investigator Responsibility

While much attention is paid to the role institutional committees play in the research process, ultimately it is the principal investigator upon whom all responsibility for the research and the associated process and regulation rests. Principal investigators (PIs) are expected to consider the proposed research in terms of: consistency with the mission and goals of the AHC, scientific merit, and feasibility (including financial, clinical and lab facilities, the pool of patients etc.). PIs are expected to define the research team and to assure the qualifications of associate investigators to perform the studies. PIs must insure that these and any other responsibilities are clearly understood by all parties when they delegate authority. It is the responsibility of the PI to develop and negotiate with the sponsor a budget that is adequate to pay for all costs of the study (including indirect cost recovery). PIs are required to identify subjects protection issues, environmental health and safety issues, potential conflict of interest issues, and to apply to the various review committees for approval of the same. PIs are required to be aware of and to comply with research regulations during the application phase and throughout the "life" of the research project. Financial management of the research account is often shared between PIs and department administrators. There is variability among investigators and across departments in how well these research process responsibilities are met. PIs are often not aware of the scope of their responsibilities nor the consequences of failures to fully adhere to these responsibilities. Even if faculty are fully aware of all of these responsibilities and consequences, many PIs do not have time or trained staff to carry them out. Additional problems are unknowingly created when department administrative or other staff, to whom PIs delegate some responsibilities, are too far removed from the performance of the research project to achieve the desired or even adequate oversight.

1.2.3 Subjects Protection Programs - Human Subjects

For a variety of reasons, in all but a very few cases, the minimum length of time it takes the Institutional Review Board: Human Subjects Committee (IRB) to review and approve a study application is 45 days. It is not uncommon for months to elapse before a study is approved. Much of this "cycle" time is really down time during which not much active effort is being put toward the process. This time tends to represent time of mailing, response time of PIs, getting the study back into the queue for review, etc. The approval process is extended by the time it takes IRB staff to develop responses to initial applications and research investigators to develop responses to stipulations which must be addressed prior to getting approval. While there are a number of IRB panels, each panel meets only once per month. This meeting schedule, combined with drawn out cycle times involving communication between research investigators and the IRB, results in delays that are frustrating to faculty and increasingly unacceptable to research sponsors. The IRB process appears to be one in which much improvement could occur in time management with no compromise in quality of IRB decisions. There is also a concern on the part of faculty about the variability of review within and between IRB panels. Regulations and guidelines concerning the use of human subjects do not change frequently, but the application of these regulations and guidelines, and the definition of "local standards" varies between IRB committee panels.

1.2.4 ORTTA - Patents and Technology Marketing (PTM)

Patents and Technology Marketing for the AHC is under-resourced. There appears to be a shifting of royalty revenue from AHC PTM to support other activities not directly benefiting AHC faculty. This has long term adverse consequences for the AHC and, in fact, the University. As but one example, for a variety of reasons, Patents and Technology Marketing currently turns away 75 - 80% of the disclosures received each year. Patents are filed on the remaining 20 - 25% of disclosures. Decisions about filing patents are influenced, primarily, by the imputed value of royalties expected to be received for the technology. Therefore, among other things, budget constraints and the very reasonable desire to have "licensable technology" may hold down filings to the patent and trademark office. Greater than 90% of royalty income to the University comes from technology discovered by faculty in the AHC. This being the case, one wonders why resources are not redirected to support AHC PTM and/or cut back in other areas? It appears that PTM personnel also have their time divided by having to respond to distractions that compromise the overall time they have available to aggressively market faculty technology. Some of these distractions involve getting into resolving perceived conflict of interest issues, including time spent responding to issues raised by the current CRC, and numerous other things that appear to encumber the time to do what may be their most important function - marketing technology and services and facilitating and promoting entrepreneurial activity of faculty.

While a cursory review of royalty income and licensing fees may provide one measure of the performance of ORTTA's patents and technology marketing function, there is considerable evidence in the U.S. and abroad that this may not be the best way to evaluate performance. In fact, it may even be misleading. A summary of reports dealing with this (available on various web sites) is excerpted as an appendix. A theme running through a number of these documents is that the greatest value of university technologies is not necessarily represented in the form of royalties and licensing but rather in generating entrepreneurial activities. It suggests there is greater value, or that it may be more relevant to examine the investment in enterprises or parts of businesses focused around a university faculty member's technology than simply waiting for and tallying royalty income. Most university-derived technology is very early stage and, as such, requires much time and money (generally many, many years) before any royalties might be realized, i.e., it might be 7 - 10 years.

It appears there is little to no activity on the part of PTM in promoting these entrepreneurial activities. In fact, because of PTM/ORTTA getting involved in various other areas such as the area of conflict of interest, the University may actually suppress these types of entrepreneurial activities. This is paradoxical as this may be the most important paradigm for promoting and deriving value from university faculty technology. The increase in entrepreneurial successes and the proliferation of numerous high technology companies with high paying jobs in the Palo Alto area and the greater Boston area speaks for itself. There have been few to no companies in recent (and even not so recent) years that have been started based on AHC faculty technology.

1.2.5 ORTTA - Sponsored Projects Administration

The performance of Sponsored Projects Administration (SPA) responsibilities appears to be compromised by a staff insufficient in number to manage the volume of projects, and by the variable quality (not from a scientific standpoint of view) of applications and supporting materials faculty send to SPA. The SPA proposal and award processes for industry-sponsored research take, in the best case, several weeks and, in the worst cases, several months. For many

reasons, much of this is "down" time with little to no activity on any given grant proposal, sometimes because SPA may get a batch of grants at one time. SPA staff spend much of their time reviewing industry-sponsored project research agreements for intellectual property and publication rights. Once reviewed, changes to the research agreements must be renegotiated with the faculty member and the corporate sponsor. One of a number of circumstances exacerbating the problem is that SPA staff time is diverted to the review of confidentiality agreements and material transfer agreements while the backlog of proposals they must process often continues to grow. Indirect cost recovery (ICR) negotiation (while ICR is rarely, if ever, negotiable) is an added burden for SPA staff managing industry-sponsored research. Frequently, for obvious reasons, corporate sponsors will attempt to downwardly negotiate this. In summary, there are many time consuming, sometimes complicated and competing demands on SPA staff which make their work difficult to prioritize. Also, because of other "unlinked" university processes, how and when SPA receives proposals causes problems in its own right in that they frequently get a large group of these at one time that have accumulated in the Conflict of Interest Committee.

1.2.6 Coordination of Clinical Trials Review Processes

There is no overall coordination of clinical trials in the institution. One area performing clinical trials is the General Clinical Research Center. Recently, the Cancer Center has established a protocol review committee. All other clinical trials falling outside of these areas are developed on an ad hoc basis. There is little opportunity to negotiate internally to aggregate any of the support services needed to perform these studies, so there is no discount on hospital beds, lab or other services. There is also great difficulty finding space for a patient where they may need to be in the institution for a few hours, e.g., 2 - 8 but not for a full day.

1.2.7 General Clinical Research Center

The General Clinical Research Center (GCRC) is an important component of the AHC. It is designed and funded by the NIH to assist faculty wishing to conduct clinical research in a very controlled setting. Unfortunately, the GCRC is used for no more than 5% of the clinical research in the AHC. The primary objective of the GCRC is to support investigator initiated, hypothesis driven clinical research. Because of this and the responsibility it has to fulfill this function for NIH, the GCRC appears to have ambivalent views on the desirability and the amount of corporate sponsored research it wishes to incur. The ambivalence is seemingly related to the fact that supporting corporate sponsored research is not the core mission of the NIH sponsored GCRC. On the other hand, corporate sponsored research trials are a source of revenue for the GCRC and fill up excess or unused capacity of the GCRC and its staff. Overall, however, the GCRC appears to function in a way to make it somewhat difficult for PIs wishing to do corporate sponsored research. One disadvantage to using the GCRC for industry-sponsored clinical trials is the daily charge of $725 for each hospital bed. This daily rate is not competitive with what corporate sponsors can get at other institutions. As a consequence, the AHC is losing industry-sponsored clinical research opportunities that involve the need for inpatient space. Another disadvantage is that the GCRC has its own review committee that passes judgment on whether a given study can be performed in the GCRC or not. Often the GCRC review committee will not accept FDA approved industry protocols. In cases in which the committee grants approval, the time necessary to obtain approval may span an average of 2 - 3 months. Other possible overarching disincentives to using the GCRC are its location on the 2nd floor of the Masonic Cancer Center, where it is out of the mainstream for most clinical staff, and the age and general condition of the facility.

1.2.8 Monitoring Compliance with Research Regulations

Monitoring compliance with research regulations at the University of Minnesota is limited almost exclusively to the approval phase of the proposed research. Compliance monitoring by institutional committees and university officials over the life of a research project is limited (in the case of the IRB) or non-existent. Principal investigators and the IRB staff are expected to become aware of and to comply with federal, (and state or local, if applicable) regulations and institutional policies related to sponsored research. Principal investigators are provided little, if any, training or support in developing a knowledge base about all regulations upon which investigator based compliance strategies can be formed. It is difficult to imagine that more than a very few principal investigators would be completely and thoroughly aware of the myriad of requirements expected of them or of the full consequences of not adhering to them.

1.3 Recommendations

One of the critical observations made by the Research Support Service Taskforce is a pervasive lack of performance criteria for almost each component of a research contract: submission, approval and execution of the research. We are struck by the fact there is little, and in some cases no, regard for the value of time.

Overall, the Taskforce recommends the following actions:

- Establish very rigorous performance criteria for each office, unit, or committee that is involved in initiation, approval, performance and closing of research projects sponsored by outside corporations. Assume that professionals in these offices have the authority they need and hold them accountable. Overall, there is a need to adopt more of a service mentality on the part of all staff.

- Establish a parallel review and approval process for all internal approvals and committee reviews. In negotiations, no 24 hour period should expire without the appropriate university official contacting both the corporation's representative and the university faculty member. It is the expressed goal of the-Research Support Service Taskforce to have the internal review and approval/denial process of all aspects of industry-sponsored research applications to be completed within 10 working days of application submission, without sacrificing the current high quality of the review.

- Establish a process in which an activity sheet will be placed on the front of each contract or grant that tracks time in and time out with a uniform office stamp. Professionals in the office would initial as things move along. In turn, this would establish a log of all actions and time taken to accomplish the work. Once this became routine it would not be very obtrusive. This is much the way other professionals such as lawyers and accountants work. Failing to institute such a tracking process would make it hopelessly difficult to evaluate performance and timeliness through the various offices, committees, etc.

Detailed recommendations are provided throughout this document. The following specific recommendations address the improvements and changes that emerged from and correspond with the principal findings.

1.3.1 Disband the Conflict Review Committee

Establish a new, AHC wide committee to review conflict of interest issues (disband the current Medical School Conflict Review Committee immediately within an interim procedure developed). This committee should be named the Conflict Review and Management Committee (CRMC). The CRMC will

include representatives from the AHC schools all of whom will have had research supported by corporate sponsors, representatives from either industry or government, and one non-voting representative from ORTTA. Other configurations of this committee might be as or more desirable. The CRMC should have a redefined role and much more restricted scope of responsibility than the Medical School Conflict Review Committee. The overall objective should be to manage any real or perceived potential conflicts of interest or commitment. The CRMC should develop management plans to assure scientific integrity to the highest degree possible when a conflict of interest may be determined to exist. These management plans should include review of study data by scientific advisory boards or peer review committees, and random reviews of research conducted by potentially "conflicted" investigators.

University policy should allow faculty to have recourse and department heads, directors, and deans to give authority for review of potential conflict of interest to a central research conflict management review and support group.

1.3.2 Establish a Research Support Service Office

The AHC should establish a Research Support Service Office with a director reporting into the provost's office. This office should provide research support to investigators who want assistance with industry-sponsored research processes from initial idea to final report. The Research Support Services Office staff's principal task is to facilitate and expedite research processes for faculty in grant application, committee approvals, budgeting, etc. The research support service office should share with principal investigators the responsibility for determining the financial viability, and assuring regulatory compliance of all research projects. The Research Support Service Managers will assist and partner with principal investigators in preparing and submitting proposals; reviewing clinical research protocols; preparing regulatory documents and applications for internal review committees; obtaining internal and external approvals and authorizations; developing, negotiating, reviewing and monitoring contracts and budgets; monitoring study progress; ensuring performance and compliance of the research team with the terms of the contract or grant; assuring compliance with internal policies and external regulations; directing FDA and sponsor audits; and performing all required study close-out functions. Faculty support from knowledgeable Research Support Service Managers should enhance the quality of application materials submitted to institutional committees and provide information to faculty which they may draw upon during the performance of the project. Better preparation of applications, and particularly the supporting materials, should reduce the review time and ideally obviate the need for the recycling of proposals among institutional committees. Providing better information to faculty should improve compliance with research regulations before a process for spot checking or monitoring by the AHC is established.

The Research Support Service Office will also provide the business development services listed below.

1.3.3 Establish a Business Development Office

The AHC should better coordinate, promote, and serve faculty in their efforts to seek corporate sponsored research. The AHC should set goals consistent with its mission that complement research and discovery.

The Taskforce recommends developing a Business Development Office function within the Research Support Service Office. See Figure XYZ below depicting this on an organization/functions chart. An external advisory board will review and provide technical or market analysis of AHC technology and services. This would cover biomedical, biotechnology, bioengineering and other human and animal health related technologies, services and products.

A subsidiary function in the Business Development Office (BDO) would be a "prospecting" function. An individual, or individuals if so needed, would have responsibility for working with faculty, department heads, deans, and center or institute directors to identify technology and services that could be protected by patents or trademarks, if applicable, and then marketed. This person's job would be to develop relationships with faculty. His/her office would be a "clearinghouse" for faculty to go for advice and services in this area of intellectual property.

The Business Development Office would also have an individual or individuals whose exclusive responsibility would be marketing of AHC faculty technology and services on a local, national or global level. Technology marketing would include among other things: licensing, research & development agreements with companies and establishment of new ventures or joint ventures with university faculty as participants, to the degree they desire this.

The Taskforce recommends that licensing and royalty income (i.e, 33% that is institutional currently going to ORTTA) and other consideration derived from AHC technology and services should be allocated to the AHC. The 33% of royalty net income that is generated from AHC technologies could be used to supplement other resources to establish a Technology Investment Pool. This pool could be used to:

- invest in promising AHC technologies and services that may have commercial value,
- match funds for industry funded research and development within the AHC,
- provide incentives to investigators for disclosures that lead to licensure and facilitate an entrepreneurial research environment, and
- take equity positions in companies starting up with AHC technologies.

The primary goal of local AHC management of its corporate sponsored service and research program should be to enhance the overall success of faculty through a more expeditious and user-friendly process.

1.3.4 Enhance Performance of Subjects Protection Programs - Human Subjects Review Process

To achieve more thorough understanding and, as a result, better research applications, the University should provide sufficient staff to allow Subjects Protection Programs to actively and frequently train, consult, and provide information services to the University research community. This service to faculty needs to be provided on an ongoing basis not just on the front end, i.e., grant submission. Leaders to whom Subjects Protection Programs now report (the Vice President for Research and the Director of Research Ethics and Regulatory Compliance) assume performance responsibility for Subjects Protection Programs in terms of internal performance criteria (timeliness, quality, and consistency) as well as in terms of the external review requirements of Federal agencies.

One way to recognize the importance of services performed by members of the IRB is to have committee members be paid (or have salary offset) for their service. Given the pressure on all financial resources, it is not reasonable to expect faculty or other volunteers to be able to dramatically improve performance given all their competing demands. A small number of well-trained committee members could serve on one of two committee panels. Providing compensation or other consideration, training, and performance benchmarks to panel members should create more effective and responsive committees that could meet with much greater frequency of cycles for any one panel than is currently present. Reducing the number of panels and perhaps committee

members, will increase the IRB's opportunity to be as consistent as possible in their review of research applications. Additionally, more executive level administrative staff are needed to support committee panels, manage the hoped for increased volume of research, and write the somewhat complex correspondence required.

Without compromising the quality of review the IRB review process could be made more efficient by allowing the committee panels and research investigators to interact via video-conference at the time of review of the proposal. In this way, the principal investigator could immediately address many of the questions a committee panel might have and thereby potentially remove the need for proposals cycling back and forth to the committee.

Another way to save time in the process would be for the IRB to take advantage of courier, e-mail, and fax services to get time-sensitive correspondence to and from PIs.

Setting up a web site where IRB results could be immediately posted would aid in this and could serve as an educational tool for faculty and staff to gain experience in the process from the experiences of others.

1.3.5 Improve and Expedite Contract Review and Negotiation

Sponsored Projects Administration (SPA) should identify the common problem areas in proposal and award processes. This information and instruction from SPA should be systematically distributed to the University research community, PI's, support staff, and be used to address these common problem areas. The process could be facilitated if the AHC had an on-site representative from SPA. This representative would have the authority to approve and sign contracts, establish CUFS accounts, and authorize purchases. In addition, SPA and the AHC should collaborate in developing (or revising) a standard research agreement (or if necessary set up agreements) for industry-sponsored research. Optional language for various sections should be developed and agreed upon internally as being acceptable to the University. This should aid in coming to acceptable terms with sponsors rather than starting from scratch with each agreement. There could be the development of an "expert system" that provides information to principal investigators and their staff to avoid these common pitfalls.

1.3.6 Establish a Clinical Trials Coordinating Center

It is recommended that a Clinical Trials Coordinating Center be established within the AHC. This would serve as a site for coordinating all clinical trials efforts in humans and animals. Figure XYZ shows a potential organizational chart of how this might work. For human trials, a clinical trials unit would be established. It would be "virtual", where patients could be integrated into the overall clinical operation of the new Fairview University Medical Center. Specialized research nursing and technical staff should be available to administer study protocols, perform minor procedures, manage specimens and data, and perform other trial or research related tasks. There is a need for overnight and also short stay or "day" clinical facilities. This clinical trials unit must be a service to investigators, welcome them, and assist them in the successful conduct of each study. It is believed that bundling all clinical trials together could aid in deriving the best prices for hospital beds and services. The aggregate cost of these services cannot exceed what the market will bear if the AHC is to compete for industry-sponsored clinical trials dollars.

The General Clinical Research Center and the Cancer Center each have a separate review process for clinical trials. Protocols for patients on cancer trials must be reviewed by an NCI mandated committee affiliated with the Cancer Center. All clinical trials, whether under the purview of the GCRC or the Cancer Center Protocol Review Committee or not, have many things in common. It seems reasonable that these separate review processes all be coordinated.

The GCRC could possibly function as a component of the Clinical Trials Unit and the Clinical Trials Coordinating Center. The GCRC has certain special needs that may make it difficult to function in a "virtual" manner. As the integration of UMHC and Fairview continues, where the GCRC is situated, whether it can be "virtual" and how the GCRC and other human trials units might function needs to be addressed.

1.3.7 Provide Support for Regulatory Compliance Monitoring

The AHC should develop an explicit plan to spot check or monitor and report compliance with all research regulations and policies. As is all too obvious from reading local and even national newspapers, failures to exactly adhere to regulatory guidelines, e.g., Food and Drug Administration, National Institutes of Health and others, can have disastrous and expensive consequences. Given the open, and thus vulnerable, nature of the university, it is surprising that more has not been done to remedy this situation.

Subjects Protection Programs and the Department of Environmental Health and Safety (DEHS) should implement compliance monitoring programs which span the duration of research projects. While not in the immediate purview of the Research Support Service Taskforce, for research involving humans, compliance monitoring of research not regulated by the Food and Drug Administration (FDA) should take priority over the need to monitor research that is more regulated and monitored such as industry-sponsored research by a major pharmaceutical company.

Departments, colleges/schools, and provostial units should assume greater local responsibility for protecting their interests and those of the institution in complying with the DEHS regulations. An individual in each college/school should be identified as the designated responsible party for DEHS compliance.

The AHC should provide coordinated regulation and policy update information in the form of educational training programs and by electronic means to assure that investigators are aware of regulations and changes to them.

The University should develop a reader friendly, electronic, Good Scientific Practices document to guide faculty, staff and students in their conduct of research. Clear instructions and guidance for faculty and staff is needed to inform all in how to deal with this very "charged" issue. There also needs to be better education of faculty and staff on issues surrounding scientific or academic misconduct. With respect to alleged or actual scientific/academic misconduct, the appropriate institutional authority should, at the appropriate time, without compromising the rights of complainants or respondents provide information to the institution's research community so that the experience can be shared.

1.4 Conclusion

Considerations that guided all discussions and reviews were: how can the AHC best provide service to faculty and sponsors; provide responsive administrative, management, and compliance services; and coordinate federal and institutional policies and procedures that affect sponsored research? The purpose of this review of current processes involved in corporate sponsored research was to identify barriers, bottlenecks, and weaknesses in these processes and structures, and to recommend changes, as needed, to promote industry-sponsored research in the AHC. The major objective is to promote industry-sponsored research for the faculty in the AHC.

Our principal findings show that institutional research committees and research support services must change, not to adversely impact the quality of their reviews but to streamline, prevent undue delays, and develop a "seamless" hands-off processing method so that much, if not all, of this can occur in parallel. These committees and support services play an important role in sponsored research; however, as these groups are quick to point out, the principal investigator has the ultimate responsibility to "know and do the right thing". This runs counter to the notion many principal investigators have, that research review committees and support services share their responsibilities and somehow offer protection in the event an error (of omission or commission) occurs. Failure to fully understand these circumstances creates a dissonance that has led to bad feelings, counterproductive actions and reactions, and bad press. Frequently, faculty do not have experienced staff upon which they can rely to assist them with the long lists of research responsibilities and compliance demands.

There is evidence from within the institution that improvement in our research processes, especially improved timeliness and responsiveness, is desired. There is evidence from outside the institution that improvement in our research processes is essential. In meetings with nearly all the groups about what performance change recommendations might be made, a desire and real commitment to maintaining quality and improving the functions was evident. There is also evidence that faculty could benefit from the assistance of knowledgeable support staff throughout various aspects of these research processes. PIs electing to use the Research Support Service Office will be able to assume, correctly, that their responsibilities are shared by experienced, informed, accountable staff.

FEEDBACK

Academic Health Center Homepage