Rejuvenating a Foundering Institutional Review Board: One Institution’s Story

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Abstract

This report recounts one institution’s experience in the fundamental reorganization of its institutional review board (IRB). With an appropriate approach, organizational structure, and ethos, the goals of research participant safety, regulatory compliance, and efficiency are not in conflict but, rather, mutually reinforcing. These important goals were realized because all aspects of the IRB reorganization were guided by principles: (1) expertise, (2) service, (3) credibility, (4) efficiency, and (5) accountability. This medium-sized academic IRB was successfully reorganized to increase the scrutiny of protection of human subjects and to promote efficiency and investigator services. On average, the office returned expedited submissions to investigators with approvals or queries within two working days of submission. On submissions requiring full committee review, letters and faxes were issued to investigators within 48 hours of committee meetings. This turnaround time (combined with a nine-day premeeting submission requirement) meant that investigators who had submitted new studies for full committee review received an approval, request for modifications, queries for more information, or disapproval within 11 days from the reorganized IRB. In contrast, an Office of the Inspector General study noted that IRBs in academic medical centers typically report decisions within an average of 37 days. The reforms included mechanical and operational changes within office procedure, a robust educational program for committee members, and a revamped IRB office staff that decreased the total number of office employees from five to four but that increased educational levels and skills of the staff members.

It is, according to many accounts, a fairly common story. A new administrator arrives at a university and is immediately inundated with a host of complaints and entreaties regarding one or another aspect of the institution’s operations. Increasingly, incoming administrators are welcomed with grim warnings regarding the intricate and demanding regulatory requirements that are increasingly imposed on research universities in the 21st century. This was the case when a new vice-chancellor of health sciences arrived at East Carolina University (ECU) in late summer 2002. Specifically, he was immediately greeted by a deluge of attacks on the university’s institutional review board (IRB). Complaints regarding academic IRBs are neither new nor unique to ECU, but the number and nature of the criticisms convinced the vice-chancellor that special attention and prompt action were necessary. The subsequent one-year reform of ECU’s IRB was based on a set of assumptions regarding the history and role of IRBs and a series of principles that guided the decisions of the administration and staff as the reform progressed. Given the universality of many of the challenges faced by academic IRBs, this successful process of reorganization and the principles on which it is based may provide some insight for similarly situated institutions contemplating wide-ranging reforms.

The Challenge

Faculty attacks on academic IRBs are not uncommon. However, the frequency and vehemence of these complaints at ECU were especially notable. When the new vice-chancellor assumed leadership, the IRB had been labeled incompetent and inefficient. According to reports, document submissions had been lost and study approvals had been delayed by months. The IRB committee was branded as arbitrary and anti-investigator, and the office staff was labeled unqualified and difficult. In the first months of the new vice-chancellor’s administration, he received impassioned pleas for relief from fellow vice-chancellors, deans, department chairs, prestigious researchers, faculty, and support staff. Some investigators demanded the retention of an independent or commercial IRB, a path followed by some academic health centers (AHCs).

Although investigator complaints initially sparked the reorganization efforts, there were other reasons to champion the restructuring of the IRB. Federal regulatory oversight of research activities has been increasing dramatically for a number of years. The Office for Human Research Protections (OHRP), the Food and Drug Administration, and the Office of the Inspector General (OIG) have refined their understanding of the regulations, enhanced their oversight functions, and begun to expect increasingly higher levels of rigor in overseeing research activities at the institutional level. Significantly, the OIG has explicitly called for the reform of IRBs. Research scandals at a number of institutions have further heightened public and media interest and concern regarding research that involves human subjects. Although protecting human subjects is any institution’s primary duty, it is also true that universities face an increasingly competitive research market as commercially sponsored clinical trials continue to migrate from AHCs to private physician practices.

In January 2003, ECU, under the vice-chancellor’s leadership, undertook the fundamental reorganization of its IRB. Although this story is specific to ECU and its IRB, many of its lessons apply with equal force to other universities and other areas of university operations that demand similarly increasing vigilance and expertise.
Before the Reform

In its original form, the IRB's responsibilities at ECU included reviewing studies from a medium-sized university, the schools of medicine, nursing, and allied health, and a substantial teaching hospital. In previous years, the IRB had operated under the authority of the vice-chancellor of research. The new vice-chancellor for health sciences accepted transfer of the IRB to his authority shortly after his arrival at the institution to respond to investigators' concerns and because of a personal and professional commitment to strengthen the research infrastructure of the health sciences division and the institution at large. In addition, because the other health sciences division and school of medicine produced the major portion of the funded research, the new vice-chancellor had a vested interest in an effective and efficient IRB.

The IRB faced a moderate workload for a research institution. Before the reorganization, it used only one review panel for the entire institution. The IRB committee met twice a month. The number of research protocol submissions totaled 434 in 2003, 512 in 2004, and 662 in 2005. Biomedical research protocol submissions constituted approximately 41% of the workload, and the remainder would best be classified as behavioral or social science proposals. In 2003, approximately 20% of submissions required full committee review, 30% received expedited review, and 50% were processed and received an exempt designation after review by the IRB chair. Approximately half the studies requiring full committee review were commercially sponsored; the remainder received cooperative group or other government funding.

Before the reorganization, the IRB did not employ an administrative director. Instead, the MD chair of the IRB was the highest-ranking official associated with the IRB office. The MD’s home clinical department received payment from the practice plan in exchange for 50% of the physician’s time, which was committed to the IRB. Over the years, the chair’s role had been filled by a pathologist, an endocrinologist, a trauma surgeon, and a pediatric oncologist. Because of clinical commitments and committee and review duties, the MD chair was restricted by time to a limited role in office operations and policy development. Contact between the IRB chair and previous vice-chancellors had been traditionally limited to rare and sporadic meetings. As a result, the IRB office operated with limited day-to-day oversight from the chair, and the IRB as a whole functioned with very little oversight from the administration.

Sources of IRB funding included reviewer fees from commercial drug studies and funds allocated for review services by ECU’s affiliated teaching hospital. Practice plan funds were used to reimburse the chair’s home department for his or her time. IRB review fees were collected on commercial studies only. Fees were not assessed on government-funded or investigator-initiated studies. Although the IRB was responsible for the review of all human research at the university, before the reforms, operating funds were contributed only by the health sciences division, the teaching hospital, and the commercial sponsors of clinical trials.

Guiding Principles of the Reform

IRB offices are faced with three central demands that may seem to be in tension: protection of human subjects, efficiency of operation, and compliance with regulations. But with the appropriate mentality and organizational structure, protection of human subjects, regulatory compliance, and efficiency are not in conflict; rather, they are mutually reinforcing. During early strategy sessions, the vice-chancellor and his team became convinced that all of these goals could be furthered if the IRB reorganization and operation were guided by five related principles: (1) expertise, (2) service, (3) credibility, (4) efficiency, and (5) accountability. The success of the reorganization rested on the conviction that investigators and the institution would be willing to accept and even welcome more rigorous oversight from a reorganized IRB, because such oversight would be accompanied by more efficient operations, an improved service ethos, and a revamped IRB staff with higher levels of expertise, credibility, and accountability. In this way, the reorganization could provide the institution with a more scrupulous and conscientious IRB and faster and more sophisticated service to the research community.

First Steps

As a first step, the vice-chancellor created the new position of director of the IRB and appointed a tenured PhD/JD faculty member from the medical school ethics department to lead the IRB during the one-year reorganization period. The director’s full professor status, strong research record, legal training, and many years of experience as an IRB member exemplified the vice-chancellor’s commitment to providing the necessary resources to bring expertise and credibility to the IRB. Working closely with the vice-chancellor, the director initiated a series of actions designed to symbolize and reinforce the office’s commitment to service and efficiency. At the vice-chancellor’s direction, the new director met individually with deans, center directors, clinical chairs, principal investigators, and clinical coordinators to assure them that they should recognize immediate changes in IRB performance and to determine what reasonable reforms and practices would most aid their research efforts. The director encouraged investigators and their staffs to hold the IRB office responsible for avoidable inefficiencies in processing the review of research projects and promised to establish reasonable deadlines for the processing and review of studies. To hold the office accountable for its performance, the director immediately established a comprehensive system for tracking and recording all stages of a research proposal's life cycle through the IRB process. In a major break with the past, the director apprised the vice-chancellor of the reform efforts both in written reports and in face-to-face conferences, first in weekly, and then later in monthly meetings.

Office Personnel

With the ECU IRB’s commitment to reorganization came the decision to hire an IRB staff with the requisite expertise to understand the relevant regulatory responsibilities of the office and, at the same time, understand and be committed to the research enterprise. The vice-chancellor and the reorganization team reasoned that the performance of the institution’s IRB had suffered because of a fundamental misperception of the nature of the required work. The level, quality, and character of resources committed to IRBs have, to some degree, reflected the level of scrutiny and
oversight applied to human-subject research in general. Early IRBs, in the 1970s and later, were characterized by small staffs, most of whom were clerically trained. These staffs were unable to keep up with the increasing workloads as IRBs began to play bigger roles in academic institutions. At the same time, the level of regulatory scrutiny of IRBs, official and unofficial, increased dramatically.

Although many institutions began to increase the number of staff assigned to help IRBs fulfill their paper-flow functions, IRB staff were still inadequate because staff members remained low paid, untrained, inexperienced, and clerical centric. This approach, however, created a number of problems, both in terms of regulatory compliance and efficiency. As regulatory demands became more sophisticated, IRBs staffed with clerically trained workers could neither answer technical questions regarding research, nor could they problem solve on case-by-case bases. When asked to read and interpret nuanced and evolving regulations, law, and guidance documents, IRB clerical staff sometimes tended toward literal and mistaken interpretations of research requirements. When a staff member departed, he or she was frequently replaced with another inexperienced or untrained individual. When judgments are made on regulatory documents by individuals without the requisite experience, training, and background, the resulting guidance can be either over- or underprotective of human subjects. The former unjustifiably handicaps an investigator, and the latter may endanger subjects and violate federal regulations.

Before reorganization, the IRB boasted five full-time office staff members—a credible number of employees. However, none had college degrees, and four had been employed in lower-level clerical positions elsewhere at ECU. The fifth staff member had advanced from a clerical position and had a number of years of experience with IRB operations. However, none had previous clinical, research, or regulatory experience. Although an MD served as the chair of the IRB, it was this staff that made most of the day-to-day decisions regarding research regulatory issues.

Within six months, the four office administrator positions had been eliminated and replaced with more experienced and knowledgeable, albeit more expensive, staff positions. An RN with graduate training in public health, 10 years of clinical experience, and a stint as an IRB administrator was appointed associate director. Significantly, the associate director had also served as a clinical trials coordinator running medical device studies. The second new staff member had run clinical pharmaceutical trials on an outpatient basis for five years and was finishing her graduate training in public health. A third initial hire had clinical training, a graduate degree, and multiple years of managing and monitoring clinical drug trials for a major pharmaceutical company. With this team in place, the IRB could boast hands-on clinical trials experience in drug and device studies, inpatient and outpatient studies, and commercially sponsored projects.

Although this new staff commanded far more salary resources than the one that it replaced, the results were easily worth the expenditures. Clients of the office could speak to staff members as colleagues who clearly understood the federal regulations as well as the realities of the research process itself. The new staff could preview submissions and help devise solutions for investigators who wished to make their proposals comply with IRB policy. The ability to understand the research environment, research proposals, and the required regulatory requirements also allowed the staff to increase the speed and the proficiency with which research proposals were processed through the system. Because the staff had all recently been involved in the research enterprise themselves, they understood the time-sensitive nature of research work. The net result of a refurbished staff with more expertise and experience was nothing less than transformational.

First, submissions to the IRB improved because IRB staff members were able to provide technical and practical services for trial coordinators and principal investigators as they prepared their studies and the required documentation. The submissions more compliant with human-subject protections and regulations could be processed through the IRB system with more efficiency because many or most oversights had already been resolved before the submission reached the IRB committee for review. In an address on behalf of the Association of American Medical Colleges, research ethics pioneer Robert Levine emphasized that “IRBs were established to work collaboratively with investigators, the vast majority of whom are altruistically motivated and intend to do the right thing.”

Enhanced staffing allowed the IRB office to interact with investigators as collaborators instead of antagonists, and, as a result, protection of human subjects, regulatory compliance, and efficiency all improved. Second, as IRB staff helped investigators through the process, the office’s credibility improved. Investigators were more willing to make changes because they had the confidence that the IRB staff understood what the federal regulations required. Third, because the staff worked with investigators and the regulations on a daily and intimate basis, they were able to play a central role in rewriting and enhancing the practices, policies, and procedures of the IRB. Fourth, the staff’s newly enhanced intellectual capacity allowed it to establish strong lines of communication with federal agencies to better determine regulatory expectations. Finally, the new office staff initiated a focused, educational effort. Office staff met quarterly with clinical trial coordinators to train and update them. In addition, to support the professionalization of research at the institution, the office staff helped spearhead a move to establish a local chapter of the Association of Clinical Research Professionals. Office staff presented educational sessions in departments and research units in all areas of the university and hospital campuses. Instead of providing a one-size-fits-all generic presentation, the IRB office provided prospective researchers with specific information and guidance that was tailored to their respective disciplines and areas of research. Office staff designed and offered focused presentations for such disciplines as cardiology, pulmonology, rehabilitation, pathology, and trauma. Although all research involving human subjects must conform to the regulations, each arena of research presents unique challenges. Again, this focused approach to investigator education enhances collegiality, efficiency, compliance, and, most importantly, protection of human subjects.
The IRB Committee

Despite its flaws, the existing IRB committee had many strengths, including a large number of experienced and committed reviewers. As a result, reorganization efforts focused on reforms that would enhance the committee’s performance and support its work. The reorganization, for instance, created an additional IRB review panel devoted solely to the review of behavioral and social science protocols. A full professor of psychology was named as the director and chair of this committee. As a result, biomedical and behavioral and social science proposals received more specialized review. Members of the new behavioral and social science research IRB were selected according to faculty interest and experience in research and were intended to represent the range and scope of disciplines whose work might be reviewed by the group. The new committee included members or alternates from the departments of criminal justice, English, social work, nutrition, anthropology, ethics and law, nursing, psychology, and education.

Because the existing biomedical panel already boasted a fairly strong clinical and nonclinical presence, the reorganization focused on removing less contributory members, increasing the representation from missing subspecialties, and reforming the culture of the committee. A pediatric oncologist with extensive clinical trial experience served as chair and medical director. In addition, after the reorganization, the panel boasted either full or alternate members in the diverse areas of surgery, general pediatrics, nursing, adult oncology, trauma, vascular surgery, neonatology, infectious disease, obstetrics–gynecology, psychiatry, orthopedic surgery, general medicine, pharmacy, biology, and critical care. Research protocols were assigned by office staff according to the knowledge and experience of the reviewers. When a research protocol required special expertise not represented on the committee (i.e., endocrinology), the IRB office maintained a list of internal consultants who were willing to provide written advice on the research proposal in question. Such studies also were assigned to the customary primary and secondary reviewers, and the consultant’s report was typically forwarded to the entire committee.

The committee maintained a broad list of nonclinical and nonscientific members and alternates from the ECU community as well. These members were chosen on the basis of their understanding and interest in the research process, their knowledge of human subject–protection regulations, and their apparent ability to review research proposals with an eye for relevant detail. The nonscientific and nonclinical reviewers included an ethicist, a technical writing professor, an epidemiologist, a health education specialist, and a chaplain. Two new community members were recruited from local schools and churches. Both possessed graduate training, but, more importantly, both were willing to speak out and engage in conversations about complicated, difficult, and sensitive issues in front of a committee of professionals. Given the unfortunate experiences of many community members who had previously participated in IRBs, the IRB director and staff met with the new community members a number of times to encourage and nurture their full participation and provided them with a range of educational materials to increase their understanding and comfort level.

A series of largely mechanical reforms were introduced to enhance the performance of the reviewers and committee members. Committee members receive review materials seven days before scheduled meetings. Primary and secondary reviewers are asked to produce written reviews and to complete electronic reviewer checklists developed by the office staff to outline and document the required regulatory considerations for each study. Reviewers submit the completed checklist along with their written reviews, questions, comments, and recommendations via e-mail to the IRB office 48 hours before the meeting.

Armed with this information from primary and secondary reviews and with the information gleaned from the in-office review process, the IRB office staff contacts the principal investigator or trial coordinator and secures answers to outstanding questions and potential solutions to concerns. In many cases, these questions are resolved simply or with the submission of additional materials. In the event of substantive questions regarding the study, the principle investigator is invited—but not required—to attend the meeting at which the study in question is discussed. The benefits of this close interaction among the IRB office, investigator, and IRB committee enhances the sense of collegiality, promotes a fuller understanding of the study, and provides a means of answering questions before the committee meets and deliberates.

Before the reorganization, questions and concerns not raised and resolved before the meeting would ordinarily have waited two weeks until the next scheduled IRB meeting for resolution. After the reorganization, the primary and secondary reviewers’ typed comments are now projected via LCD display and notebook computer during the meeting for the entire committee to view during the oral review and discussion of the proposal. If the office staff receives additional information or explanation from the investigator’s team, that information is included in the display for the entire committee to view and consider.

Despite the generally high quality and work ethic of the individuals who served on the IRB committee, reviews, deliberations, and decisions still suffered under the old system from a recurring inability to identify and unravel the most relevant and pressing issues in a research proposal. Some reviewers, for example, might have identified noncritical punctuation errors or anomalies in internal processing documents that would never be seen or read by a human subject, or required consistent use of capitalization throughout an informed consent document. In addition, the committee would sometimes change language that had been approved on a virtually identical protocol in previous weeks. The solution to this problem was multifaceted. Senior staff members, including the director, attended all meetings to serve as informal “historians” to remind committee members of their rulings on previous wording changes. Second, the office worked to ensure that a more consistent set of attendees would serve as the core of the IRB committee. Before the reorganization, all members and alternates were invited to attend meetings, but this approach increased the number of arbitrary comments and decreased the consistency from meeting to meeting. After the reorganization, only
those members and alternates who were necessary for quorum or were voting and/or reviewing studies would attend meetings. This created a core group that could bring both consistency and expertise into the process. When the committee accepted consent language on an issue that recurred in other studies, the office staff, with concurrence of the committee, memorialized that language in boilerplate language so that the committee would recall their previous debate and actions. Similarly, the office staff developed an elaborate glossary of “lay language” for informed consent documents that had been approved by the committee.

Office staff created other review aids to guide the work and reasoning of the committee. Some research projects raise special considerations or require explicit, regulatorily defined findings by the committee. For example, pediatric studies require findings related to the level of risk and the number of parents required for the consent process and documentation. The use of placebos also requires explicit findings by the committee. The office staff developed a series of templates to query the reviewer and committee members as to the required deliberations and findings for these studies. In this way, the reviewer and committee members can systematically consider and confirm that the required elements are present. These templates are inserted electronically into the reviewer’s document, which is projected via LCD and laptop computer at the committee meeting. This projected template with the reviewers’ and committee members’ discussions and conclusions becomes part of the official minutes of the meeting, which memorialize the deliberation and conclusions.

Finally, the IRB administration and office staff undertook a coordinated and comprehensive reeducation program of existing members of the committee. All IRB committee and staff members were required to take the online Collaborative IRB Training Initiative program developed by the University of Miami. In addition, committee members and alternates were provided a commercially produced IRB member handbook. The “IRB 101” educational materials developed by Public Responsibility in Medicine and Research were duplicated with permission and distributed to all members. Every IRB meeting included a journal article, regulation, or guidance document selected by the office staff for discussion and further educational development. When possible, the educational issue for discussion was keyed to and selected to answer a question that would be raised by one of the research proposals scheduled for discussion at the same meeting. In this way, members were provided ongoing, specific, and relevant education that was reinforced by the application of the principles to a study under consideration at the same meeting.

For new committee members who were recruited, the IRB office developed an informal stepwise education and training plan. New members were provided the standard educational materials, and they also were “coached” for a number of weeks by the director or another high-level office staff member. Discussions would include review philosophy, the relevant regulations, ECU’s policy and procedure manual, and an overview of the process of review and approval. New members attend one to three committee meetings before receiving an official assignment. After initial meetings, a new member might be assigned as an informal third reader to supplement the primary and secondary reviewer. Before the meeting, a senior staff member and/or the primary and secondary reviewers would often discuss the new reviewer’s comments on the proposal with the new reviewer. The new member would be able to hear at the committee meeting how his or her insights meshed with those of the committee and the primary and secondary reviewers. After this stage, the new member would be assigned as a secondary reviewer on a relatively uncomplicated study, with the primary reviewer and office staff acting as mentors. This stepwise process provides a quasi-formal program of initiation and education in place of the education that new members had previously received simply by observing veteran committee members. This structured process allowed the administration to change the culture of the committee in ways that both enhanced efficiency and, more importantly, focused reviews on the protection of human subjects.

Results and OHRP Site Visit

Within a year of the reorganization effort, it was undisputed that the IRB was operating in a different way than any in institutional memory. The IRB set and met expected timelines that rivaled any academic IRB in the country. The deadline for submitting new proposals to the IRB office for full committee review was nine days before a committee meeting, which was shorter than the vast majority of IRB submission deadlines in the country. In fact, further shortening of the submission deadline is ill advised and would limit the amount of review time available for IRB committee members. Because of inconsistent record keeping, it is difficult to provide reliable comparative data on the IRB’s performance before the reform. But a postreform review of the actual time taken by the office on submissions in a year demonstrates an impressive record of efficiency and attests to the success of the reorganization. In January 2005, the director evaluated the office’s performance for the previous year (January to December 2004). The time between an investigator’s submission and the IRB office’s response was calculated for the entire range of functions performed by the office.

According to the audit, the IRB office informs the investigator of full committee actions—approvals, modifications, or requests for additional information—by letter and by fax within 48 hours of the IRB meeting. The 2004 audit data for full committee actions reflected this target. For example, full committee actions or queries on new studies were returned to the investigators by fax and letter an average of 1.3 working days after the committee had met; full committee actions on revisions took an average of 1.7 days, full committee renewals 1.4 days, and full committee approval of required modifications two days. 2004 data demonstrated that IRB performance on other required functions had also improved. In cases of expedited reviews—new studies, revisions, renewals, and modifications—investigators received a query requesting further information from the office or a letter via fax and mail, on average, within two working days of submission. Closures were processed and confirmed 1.6 working days from submission, and adverse events and safety-monitoring
board reports were reviewed by the MD chair of the biomedical IRB within 1.7 days of receipt. The reorganized IRB provided investigators who had submitted projects requiring full committee review with an approval, request for modifications, queries for more information, or disapproval within 11 days of submission of the materials to the IRB office. In 1998, the OIG noted that the IRBs in the AHCs they had visited required an average of 37 days to report their decisions. Anecdotal reports from some AHCs are even higher. An 11-day “turnaround” is compatible with the rates the OIG found for commercial, independent IRBs.13

Of course, the true test of an IRB’s performance is whether it effectively and efficiently achieves its primary responsibility of protecting human subjects. In March 2004, one year after beginning the reorganization process, the institution requested a voluntary quality-improvement site visit from OHRP.14 OHRP quality-improvement site visits, which last two days, are distinct from the random and for-cause audits conducted by the office. They are designed to provide IRBs with insights into their progress and ways in which they can improve their work.15 In March 2004, a two-person team from ORHP conducted a two-day site visit at ECU. The team interviewed administration, staff, committee members, and investigators. The site visitors reviewed policies and procedures, randomly pulled and reviewed study folders, and analyzed committee meeting minutes. The team devoted a significant amount of time to discussing specific issues and policy requirements with the staff of the office.

The site visit was an extraordinarily useful exercise. The site visitors’ written report provided valuable insight into ways in which policies, operations, and processes could be refined and improved. The office subsequently integrated the site visitors’ recommended changes into the policy and operational framework of the IRB. However, one of the audit team’s more general observations holds special relevance in this narration of the reorganization. In their exit-visit interview with the vice-chancellor and the director, the site visitors said they were especially impressed with their discussions with the committee and the IRB office staff, and that the IRB was “the most engaged” one they had encountered. This particular plaudit is perhaps the most important of any provided by the team because it is emblematic of the philosophy of the reorganization.

Costs of the Reformation
The reorganization of the IRB required both one-time and ongoing financial investments. However, total operating expenses after the reorganization were easily within the median IRB expenditures for other AHCs reported in the literature.16 The underlying operating expenses (supplies, telephone, photocopying, and utilities) did not increase after the reorganization, nor did the recurring cost of reimbursing a clinical department for 50% of the time of the full professor clinical faculty member who served as IRB chair. The latter costs were paid from practice plan funds. However, there were other significant shifts in expenditures.

There were two substantial one-time expenditures associated with the reorganization. First, the university spent approximately $32,000 on IRB software and servers to enhance the office’s record-keeping abilities. This expenditure was drawn from facilities and administration funds. Second, the reorganization required the services for two years of a tenured PhD/JD faculty member from the school of medicine. This professor was paid his full salary for two years, as well as a 35% stipend to serve as director and to help design and oversee the reorganization. The costs for the director of the reorganization were collectively borne by the faculty member’s home department, revenue from IRB review fees, and the practice plan. When the bulk of the reorganization had been completed, the organizing director returned to his home department, and a director was named from the IRB office staff. At this point, compensation for the director became part of the IRB’s ongoing salary structure.

The reformed IRB office required two significant ongoing expenditures as well. As mentioned above, a key component of the reorganization required the employment of more highly skilled staff at higher salaries. Ongoing costs reflect this philosophy. From 2002 to 2003, the IRB office employed five staff members at a cost in salary and benefits of approximately $152,400. Since the reforms, in 2006 and 2007, the four new employees have collectively received approximately $229,000 in salary and benefits—a permanent payroll increase of nearly 34%, with one fewer staff member. As another ongoing expenditure from the reorganization, the new behavioral and social science director and chair is provided a 10% salary stipend and is granted reassignment time from his or her home department at a total annual cost of about $32,000.

As a result of these two expenditure increases, total spending for the IRB increased from approximately $272,000 before the reorganization to $379,000 after the reorganization. Fortunately, these new costs have been partially offset by new funds. Funds contributed by the teaching hospital increased during the reorganization, and the cost of the new social science chair was entirely absorbed by new funds contributed by the larger university in partial recognition of the significant nonmedical work performed by the IRB. As mentioned earlier, the biomedical IRB chair’s funding did not change with the reorganization and continues to be paid by the practice plan. Similarly, day-to-day operating expenses for telephone, photocopying, and office supplies were not affected by the reorganization.

A Successful Reform
More than anything else, the reorganization was built around the conviction that personnel with the appropriate intellect, expertise and insight could, with sufficient support, increase efficiency and oversight simultaneously—indeed, as two sides of the same coin. Employing intelligent and experienced staff and IRB committee members led to more engagement in the research oversight process between the IRB and investigators and research teams. Robert Levine argues that “the development of a successful IRB depends most heavily on nurturing the attitude that the IRB consists primarily of researchers’ colleagues and that its mission is to provide guidance on how an institution’s values are to be honored and upheld.” Not coincidentally, Levine also champions “a high-quality system of education for IRB staff and members.”17
be transferred to an external independent review board if internal IRB functions can be enhanced by quality staff, targeted organizational changes, and ongoing education. The reorganization’s success and legacy are in its convincing demonstration of how IRBs performing in this manner can command institutional support and credibility, thereby enhancing their ability to simultaneously protect human subjects and serve investigators and the institution.

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