

FINAL REPORT

Task Force on IRB and Compliance Roles and Responsibilities

University of Cincinnati

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CONTENTS

Charge to Task Force

Introduction

Initial Goals

1. Strengthen IRB and compliance operations and shorten timelines
2. Expand the recruitment of IRB members and enhance training
3. Improve consistency, efficiency, and reliability of reviews
4. Improve the education, training, and support available for all researchers

Core Strategies

1. Establish a joint consultation and oversight advisory committee
2. Expand electronic solutions/database applications for IRB operations and procedures
3. Establish more collaborative partnerships with academic departments
4. Institute a tiered and prioritized delivery model for IRB services to increase responsiveness and flexibility
5. Develop a greater balance between risk assessment, compliance, and protection
6. Assure efficient IRB operations and reviewer/researcher training to support consistent and reliable review outcomes and transparent monitoring, and reporting.

Appendices

IRB Task Force Report

Vice President Sandra Degen charged the IRB and Compliance Task Force to examine the roles and responsibilities of the UC IRB as follows:

- Comprehensive examination of the IRB review processes and compliance
- Review and define IRB member roles and responsibilities
- Evaluate IRB committee composition for the three IRB committees
- Assess communication procedures between the IRB office and investigators

Introduction

The IRB Task Force was convened by the Vice President for Research in response to increasing faculty, staff, and student concerns about IRB and compliance operations that included mission creep, process and communication inefficiencies, and the ongoing lack of timeliness that continues to impact sponsored and unsponsored research efforts at UC. The Task Force began by completing a needs assessment, reviewing recommendations from other institutions, and consulting with members from both commercial and academic IRBs. The IRB and Compliance Task Force has identified and archived in a BlackBoard Community an extensive collection of resource documents and reports that informed the members understanding of regional and national trends and will provide a foundation for the proposed IRB and Compliance Online Resource WIKI.

During discussions, three themes arose: 1) the global concern that the current operational IRB and Compliance structures and processes are not meeting the goals of providing efficient and expert IRB review for UC's diverse research portfolio; 2) concern over the composition and

research diversity of the IRB members; and 3) concern that some investigators are not fully aware of all their responsibilities and the recent changes in IRB and compliance expectations and procedures. The university' institutional IRB and compliance culture was characterized as one that often resembled "silos of interest" that frequently exhibited "us versus them" conflict and disagreements. The lack of a shared understanding of research compliance across stakeholder groups and the lack of capacity in the IRB and compliance systems capacity were identified by members of the Task Force as overarching cultural and functional barriers to providing more robust and efficient IRB and compliance operations. The Task Force concluded that this particular set of cultural and systems challenges can only be overcome if investigators, students, and the IRB members and staff all recognize that success will need to be built upon a cultural foundation of collaborative partnership in all phases of the research endeavor. Without an appropriate strategic investment and actions steps to rebuild the foundations of a functional investigator-IRB relationship, there will be a barrier that works against achieving the UC|21 Research Goal expanding the university's portfolio of high impact and relevant research. The Task Force concluded that efficient IRB and compliance processes and procedures operated within efficient timelines are in fact the hallmarks of high performing and diligent IRB and compliance systems. It is with this spirit of increasing the level of collaborative partnership and shared IRB and compliance objectives that the Task Force provides recommended strategies to address the core concerns we identified in our review of UC research compliance processes and overall systems operations.

As such, efficient and expert IRB operations are foundational to the ongoing success of the University of Cincinnati's research and education mission. Successful IRB and compliance

operations can only result from a partnership established between researchers, educators, IRB staff and IRB members. The facilitation of the investigator-IRB and compliance partnership is necessarily based upon a clearer understanding and implementation of the service mission of the IRB. A better developed and realized sense of collaboration between the researchers and the members of the IRB system is urgently needed at UC. The engagement of all parties in the IRB and compliance processes is critical to the success of how the university moves forward to address concerns about the existing IRB and Compliance system. The Task Force is encouraged by the recent addition of selected online compliance reporting offered through the UC Researchers Gateway. Similarly, the members of the Task Force identified the importance of a “continuous improvement model” applied to all areas of the IRB and compliance system including researcher dispositions, functional improvements, and the composition of board membership. In order for the research community to achieve increased levels of collaboration, a larger investment in IRB operations and systems support is required. Also required is a significantly expanded level of compliance education and professional development geared to respond to the needs of all UC research stakeholder groups. Without these new investments, UC will continue to lack the IRB and compliance capacity needed to serve the research mission and the Strategic Research Plan of the university. The initial re- investment in IRB and compliance needs to includes the following priority target areas: 1) increased efficiency; 2) greater consistency in research protocol reviews and communication; 3) improved timelines for protocol turnaround, and 4) IRB system investments that build the online/database capacity to the level necessary for all members of the research and compliance community to successfully conduct their research and provide high quality oversight and reporting.

Objectives and Strategies:

The IRB and Compliance Task Force identified four objectives as initial and critical first steps for improving the system, transforming communication, increasing the timeliness and consistency of the processes, and for building new capacity:

1. Strengthen IRB operations and improve timeliness
2. Expand the recruitment of IRB members and enhance training
3. Improve the consistency, efficiency, and timeliness of reviews/procedures
4. Expand and improve the education, training, and consulting support for all researchers

Six strategies were identified for achieving the four objectives as follows:

Strategy 1: Establish joint consultation and oversight by establishing a representative IRB and Compliance Advisory Committee (including faculty, staff, and students)

Why: Expanded IRB participation and collaboration is necessary in order to increase progress towards achieving the initial four objectives identified by the IRB Task Force. The Advisory Committee will help to guide the development and implementation of improved electronic procedures, the recruitment of IRB members and departmental liaisons, and monitor the expanded education and training.

Recommended: The Office of Research will establish an Institutional Review Board and Compliance Advisory Committee to represent all research stakeholders groups and support an expanded and collaborative partnership with IRB and compliance members and staff.

Outcome: The IRB and Compliance Advisory Committee will help to guide and strengthen the partnership between research stakeholder groups, the IRB and compliance staff, and reviewers.

Strategy 2: Expand electronic solutions including new web-based database applications

Why: There must be an in-place user-friendly web-based interface with the IRB and compliance offices. A functional online submission and database-driven system will allow researchers to interact more efficiently with the IRB and compliance staff and board members and streamline the online approvals/reporting, increase protocol turnaround timelines, and eliminate the need for redundant paperwork.

Recommended: Rapid prototype and implement a new and improved suite of online tools, forms, and templates; all made readily accessible via the new web-based Researcher's Gateway. Priority implementation will focus on the tools to support consistent research protocol development, efficient online submission, timely and clear review/feedback to the researcher, and tracking. Examples of items the electronic suite of tools will include a full complement of electronic IRB and compliance forms, informational process flow charts, exemplar documents and boilerplate text, best practices for discipline-specific protocols, educational content, discussion boards, and online help tools, all with database and archival Wiki-capability.

Outcome: A priority for the development and implementation of user-friendly electronic solutions will significantly improve the consistency of protocol submissions, and markedly improve the delivery and timeliness of the feedback and reporting needed by researchers and IRB staff and members at multiple points in the research cycle. The integration of research stakeholder groups in the development of online tools will

over time enhance the quality of submissions, and improve the efficiency of the submission process, the timeliness of the review and provide a database to monitor the review process.

Strategy 3: Establish partnerships with academic departments

Why: Communication between researchers and educators and the IRB staff and members must be improved. The IRB needs be appropriately staffed and supported with trained members. Each research/academic unit needs to have knowledgeable advisor liaisons to the IRB and Compliance offices. The level of support needs to be sufficient to allow timely and accurate communication between the IRB and all researchers.

Recommended: Each research/academic unit will identify and a number of faculty/staff to coordinate and guide their researchers and educators in their interactions with the IRB. Further, each research unit must be prepared to recruit the number of IRB members deemed appropriate by the IRB Advisory Committee, and in proportion to the load the unit places on the IRB.

Outcome: An increased number of faculty/staff liaisons, and an adequate number of IRB support staff, will significantly improve system operations within the research/academic unit. An adequate number of IRB members from each academic/research unit will improve IRB committee staffing and remove the existing inequities of load and improve the research diversity of the members. Direct communication to each unit via the faculty facilitator will improve the procedural and content expertise bottlenecks that currently slow the review timeline.

Strategy 4: Increase IRB flexibility and responsiveness

Why: The IRB and Compliance Offices needs to prioritize resources to develop processes that protect human subjects while at the same time implement policies and procedures that do not hinder the mission critical research and education of the university. The Task Force found similar concerns in peer institutions (e.g. Ohio State University) that identify high quality IRB systems and increased capacity as integral components of assuring consistent outcomes and high standards for the monitoring of all research activities.

Recommended: The IRB office, in collaboration with researchers and educators, and the IRB Advisory Committee will identify and implement procedures to speed the submission and review process. Especially in those cases where the current system is acknowledged to be slow and inadequate, either because of the volume and timing of protocols (e.g., for courses on research methods, for mentored research projects, for changes in research personnel and minor adjustments to on-going protocols where speedy approval is absolutely essential) or because of the constraints imposed by external funders (e.g., clinical trials) or because of the highly specialized nature of the skills needed by reviewers, in which case an external IRB or alternative process is the appropriate pathway for the review process.

Outcome: By appropriate triage and routing of protocols to new and more responsive review mechanisms, the compliance system will do a better job of equitably and speedily assessing all protocols.

Strategy 5: Commit to a new balance of resource investments, effective training, and streamlined online systems

Why: IRB staff and members will apply more consistent standards to the review of protocols. Training is also needed so that IRB staff and reviewers are able to differentiate between conditions of approval (that the researcher must satisfy) and recommendations to the researcher (that the researcher would be encouraged to respond to). In turn, researchers have a responsibility to submit protocols that contain a minimum of errors or design problems that inevitably impede approval by the board.

Recommended: IRB staff members will work collaboratively with researcher groups to promote education and will work with IRB liaisons to contextualize and differentiate education and professional development for research/academic units. The new IRB and Compliance Advisory Committee will work with IRB Staff so that education and training resources promote the service mission of the IRB and respond to researcher and IRB Board member's complaints about IRB standards and procedures.

Outcome: These efforts will result in improved submissions with fewer complaints from researchers, and a better understanding all around of the shared service mission of the IRB.

Note:

The Task Force wishes to make note of the important internal steps already underway on some of these goals by members of the Office of Research Compliance including the online Researcher's Gateway, the electronic update form, and on-site IRB counseling hours at East and West campus locations.

Appendices

Implementation Action Steps (1-6)	pp. 12-28
Selected Readings	pp. 29

1 INCREASING IRB COMPETENCE AND CAPACITY

The Vice President for Research will monitor, benchmark, and report on UC's progress towards meeting the goals identified by the Task Force, and communicate outcomes to the research community and the Advisory Committee/Board.

2 ESTABLISH A STANDING IRB ADVISORY COMMITTEE

The Office of Research will establish and support an IRB Advisory and Compliance Committee (IRBAC) to represent research stakeholders and maintain the partnership to enhance operations. The IRBAC will meet regularly to monitor progress toward completion of all goals, to develop new strategies, and significantly enhance regular communication with research stakeholder groups. The IRBAC will serve as a forum where the concerns of the research community and IRB and Compliance Staff will come together to proactively identify and resolve research and IRB concerns.

2.1 Implementation

To ensure both accountability and authority, the IRBAC will report in an advisory capacity directly to the Vice President for Research. The Office of Research will work collaboratively with colleges to ensure wide representation on the IRBAC; the committee will be comprised of members of the research community (including students) and staff members from the IRB and Compliance offices.

3 ELECTRONIC SOLUTIONS

3.1 Planned solutions

These recommendations encompass activities that have the potential for immediate impact. This is not a comprehensive list of all the potential electronic solutions. Many examples of electronic solutions already exist at UC and at other research centers. Every attempt needs to be made to adapt existing tools to improve the functionality and online capacity of UC's IRB and compliance operations.

3.1.1

The electronic interface with the IRB and Compliance operations will be designed and implemented to guide the user directly to the relevant information and forms/document templates. The creation of user friendly, decision diagrams, much like an adaptive interview logic flow diagram or clinical algorithms, will greatly simplify the navigation process as the investigator drafts each new protocol. A decision-based online system submission system will also reduce the number of protocols that are submitted inappropriately, or lacking necessary content.

3.1.2 Electronic submissions with online help

Complementing the electronic protocol submissions process with 'help files' will greatly facilitate protocol development. Directed and interactive help for individual protocol sections, with links to examples, will provide a timely and easily updated resource for investigators.

3.1.3 Example protocols

Creating an online library of IRB approved protocols will provide investigators with relevant, real world examples that can be used to demonstrate acceptable language, solutions to standard human subjects' protection problems, and common pitfalls (and how to overcome them).

3.1.4 Educational content

Passive and active educational content will be made available in electronic format. Interactive sessions making use of an electronic classroom will be implemented. Professional development and investigational resources for researchers must be readily accessible and relevant.

3.1.5 Online discussion forum and Wiki

A dynamic interface, accessible by the entire University Community, will be created to answer questions and build a knowledge base, and to provide an adaptable information superstructure. Appropriately moderated, this resource will minimize the need for resource intensive face-to-face consultancy.

3.1.6 Best practice LISTSERVS

A LISTSERV will be implemented to disseminate best practices, share common solutions and actively address new ideas and concepts. The LISTSERV will reduce the burden on individuals and on IRB members and staff by improving information flow.

3.1.7 Searchable online knowledgebase

IRB information will be archived in a searchable knowledgebase that will provide easy reference to specialist research skills and best practices in human subjects protections differentiated by research disciplines.

3.2 Caveat

Electronic solutions are a readily available means for providing information, education and consultancy. However, they will not succeed if the interface is not designed with the end users' participation. It is not sufficient to make information or content available and expect users to find what they need with little to no input and guidance. The design of the interface needs to be responsive to researchers. Experts in interface design and information flow will need to be included in development.

3.3 Implementation

Three key areas of implementation are noted: i) the electronic interface design, ii) content creation, and iii) maintenance. The creation of co-op positions within the IRB and Compliance office will provide students in communication, digital design, information technology or others with real world experience building and maintaining user interfaces while providing the IRB with a flexible resource to meet development and maintenance needs. Guaranteed budget allocation for UCIT personnel to design, implement and maintain online systems will provide a stable knowledgebase for integrating solutions over time. The IRBAC and the departmental liaisons will serve as beta testers for electronic solutions.

The electronic protocol submission process has already begun and the online Researcher's Gateway is active at UC. The discussion forum and Wiki are key functions already described in the CTSA Grant proposal, and these need to be implemented for study design, research methods and bioinformatics. Integrating the regulatory compliance and human subjects' protections components will require increased technical resources and budget. There needs to be commitment and participation from the IRB and faculty to moderate the discussion forum and translate common threads into FAQs and Wiki entries.

4 IDENTIFY AND SUPPORT AN IRB MEMBER, AND FACILITATOR FOR EVERY RESEARCH ACTIVE ACADEMIC UNIT, DIVISION OR DEPARTMENT

The ratio of individuals with expert IRB knowledge to those needing access to that knowledge is not sufficient to respond adequately to the volume of protocols being submitted at the university. The shared understanding of the IRB knowledge base is limited and there are significant gaps in the IRB's ability to respond to the diversity of research, disciplines, mixed method designs, and new fields of applied research. Also, two types of knowledge are in limited supply: expertise to facilitate the administrative aspects of protocol submission, and regulatory and ethics expertise for navigating the complex ethical issues in human subjects' research. There is also a need for experienced investigators with appropriate skills and knowledge who are willing, trained and resourced to serve on the IRB. The goal of this strategy is therefore to increase the number of experts able to support both investigators and the IRB. The Vice President for Research's Strategic Plan need to give priority to develop a plan and budget resources to expand the number and participation of a more representative pool of research and disciplines.

4.1 IRB facilitator

Identify and recruit an IRB facilitator within each of the individual research/academic unit who is knowledgeable about the IRB submission and review process, and who can provide investigators with assistance in creating a submission that meets the requisite criteria, such as ensuring completeness of paperwork. For example, a research coordinator can function as the unit's IRB facilitator.

4.2 IRB advocate

An IRB advocate is an investigator or staff member who is trained in human subjects' protections, has knowledge of the workings of the IRB office, and has methodological expertise within a specific discipline. The advocate serves as an expert resource for both the investigator and the IRB, including interpretation of rules as might be applied to innovative research models of design and disciplines underrepresented on the IRB Boards. As well, an advocate can work on behalf of the investigator to help inform the IRB of human subjects' protections in new or novel research. The individuals in these positions will advocate for the IRB among investigators, and advocate for investigators with the IRB.

Any IRB advocate will be considered eligible for IRB membership; a functional advocate pool will comprise the IRB's extended membership pool. This will also support the expansion of IRB capacity and flexibility as discussed previously.

4.2.1 Additional roles of the IRB advocate

An IRB advocate will be able to play several additional roles. An advocate member network can form the basis of a member pool for departmental Data Safety and

Monitoring Boards. IRB advocates can serve as members of peer-review committees that exist informally in some departments already and may eventually be established in many more research-intensive units. For example, within some units, protocols must go through an internal review process prior to submission to the IRB and Compliance Offices. The enhanced IRB advocate role will become an important component of the review process and add to the overall IRB and Compliance capacity of the University. Ultimately, the precise role that the IRB advocates play will depend on the development of more functional interfaces between the individual research/academic unit and the IRB and Compliance Offices.

4.3 IRB members

Each research/academic unit must be prepared to recruit and support faculty members joining and IRB committee. Members can function initially as an advocate to gain experience, and then be nominated to the IRB Board.

This recommendation is paramount to success of IRB operations: the make-up of the IRBs can only be revised to satisfy the current concerns and discontent of investigators if research/academic units are willing to support training and volunteer personnel with the appropriate discipline-specific and research expertise. Further, it is easier to train an investigator in human subjects' protections than it is to train an IRB member in the specific details of every discipline and program of research. In recognition of this, it is more efficient for research/academic units to offer a skilled researcher for IRB membership than it is to expect IRB members to become knowledgeable in every discipline.

The Task Force also found that in addition to the shortage of qualified IRB Members, there is a critical shortage of IRB Members who are willing and available to serve as the Board Chair. At the present time the *two medical IRB's* have the same Board Chair. The Task Force commends the commitment and work ethic of the Board Chair, but even with the release time provided, the volume of protocols, communication, and Board/Investigator interactions are not well served by a single Chairperson. The Task Force strongly recommends that the Vice President for Research work intensively to provide additional investments in faculty IRB and Compliance leadership development. The Task Force further recommends that each IRB have its own chair person and support staff resources.

4.4 Training of personnel

IRB facilitators and advocates will undergo training on regulatory matters and the submission and review processes. IRB advocates will undergo the same training as IRB members. As topic experts within their field of research, they are ideally suited to support the investigators' and the diversity of human subjects' protections that need to be addressed across different disciplines and research fields. IRB facilitators and advocates will receive ongoing training and to get updates and share new best practices.

4.5 Caveat

It is fundamental to increasing the capacity and effectiveness of the university's compliance systems that IRB member advocates and facilitators remain current with their knowledge; systems of online and in person continuing education will need to be in place, and communication with IRB and Compliance staff needs to be ongoing and efficient. Note that facilitators and advocates are based in academic and research units and that they serve as

resources to the community and further expand the pool of individuals available to serve on the Institutional Review Boards. Advocates and facilitators are not intended to constitute a separate or new layer in the IRB approval process.

4.6 Implementation

Implementation of these strategies and the successful recruitment of new active IRB advocates, liaisons, and members will require significant resources dedicated to training and continuous education. However, it is also recognized by the Task Force that significant resources are currently expended on trying to navigate and maintain a system that is understood by many investigators to be broken. With minimal initial investment and the recruitment of faculty, shared centrally and by the research/academic units, the development of a pool of IRB facilitators and advocates will translate to i) improved research incomes, ii) decreased resource expenditure on finding work-arounds and duplicating tasks, and iii) improved education and timeliness for faculty, funded research and for students: particularly in the approval of thesis research projects.

The IRB facilitator could also be an administrative individual who might be situated anywhere within a research/academic unit's structure. The individual must be provided sufficient time to offer support to investigators, as well as to remain current in the IRB knowledge base and procedures. Training and maintenance of knowledge will be supported centrally, while the practice of facilitating discipline specific IRB submission will be supported by the academic unit. If the support is for students conducting research as part of their coursework, this will be considered part of the educational mission.

The Task Force recommends that IRB membership needs to be rewarded and recognized in some significant manner. The following might be considered as incentives: course release time, financial awards, and the formal recognition that participation in IRB service activities is a valued component of promotion and tenure portfolios. Large research-intensive units should also consider local investments in human subjects and compliance capacity building such as the allocation of dedicate office/consulting space and increased administrative support for the development, submission, and monitoring of research protocols. Whatever methods of reward/recognition are used to increase departmental and university capacity, the new investments in IRB and compliance functionality and faculty/student participation need to be clearly stated, included in reappointment and tenure documents, and resourced at both the departmental and university levels.

5 IMPLEMENT IRB AND COMPLIANCE FLEXIBILITY INITIATIVES

There are many situations when specialist knowledge or non-standard considerations are encountered in the IRB review process. By embracing adaptive strategies within the UC IRB framework, specialized reviews can be managed more efficiently. Examples of such strategies are:

5.1 External IRBs

There is in selected research disciplines a need for using of an external IRB, such as Western IRB. This need is often driven by sponsors who are already utilizing the services of a central IRB, and who are unwilling to work through an additional IRB and duplicate effort, increase expenditure, and delay subject recruitment and clinical trials. In defined circumstances, the use

of an external IRB can facilitate and expedite the conduct of clinical trials. UC is in the process of negotiating and piloting the use of an external IRB organization.

5.2 *Sub-committees*

Creating sub-committees organized around membership with specialist knowledge or experience in defined study areas of research has the potential to maximize the consistency of both the protocols and the review process and further expedite the time spent processing protocols that fall into specialized areas of research. An example is a group dedicated to the oversight of research conducted under the Exception from Informed Consent regulations, who are cognizant of the concepts contained within those regulations and the methods investigators should be using to maximize human subjects protections. Additional foci for sub-committees include protection of subjects lacking the capacity to consent, survey research, neuropsychological testing, action research, genetic research etc.

5.3 *Specialty IRB(s)*

The Office of Research Compliance and the Advisory Board will investigate the establishment of a specialty IRB to support graduate student research to improve the outcomes and efficiency of class assignments or projects that must be undertaken and completed as a requirement for a graduation capstone, thesis, or dissertation. Additional resources will be provided to the IRB office to investigate and pilot a specialized IRB review committee.

5.4 *Explore the use of core protocols*

Creating best practices protocols that encompass the general methodology within a specific research discipline will enhance the efficiency of IRB protocol development and subsequent review for new projects. Core protocols might be lab based, or based within an academic

discipline. There are several examples of core protocols that could be made available immediately by the staff of the IRB and Compliance Offices.

5.5 Flexibility in Continuing Review

For research projects not subject to federal regulations, the University has elected not to apply DHHS regulations to all research. The IRB and Compliance needs to consider modifying its continuing review policy to provide more reporting flexibility for minimal risk studies.

5.6 Caveat

Building flexibility within a functional regulatory framework will continue to need an expert understanding of the regulations and include an efficient assessment for each new procedural improvement. Appropriate institutional oversight, provided by the IRB and compliance staff members, needs to expand to include regular and meaningful the consultation with the IRB Advisory Committee. Further, elements of flexibility described above require significant trust between the University and other institutions, and between the University and investigators; there is a potential for misuse and error if flexible systems are not appropriately monitored. The IRBAC will assist with the ongoing review of these initiatives and monitoring their implementation.

5.7 Implementation

The first step in developing a more flexible set of solution is outlining the scope of work and regulatory basis for change and improvement. As an example, the IRB is allowed latitude in setting the interval for continuing review for minimal risk studies. There are several options available, ranging from intervals of greater than annually to eliminating continuing review entirely, depending upon the specifics of particular protections.

The next steps are solution strategy development, identification of resource needs, and then implementation (the ultimate decision to implement a flexible solution must rest with the Office of Research Compliance, and this office should be involved in the evolution of such strategies). Prior to implementation of any strategy, it is recommended that the Office of General Counsel review the plans in the context of the regulations to ensure any liability is limited.

Needs identification and strategy development are well within the existing purview of the IRB and Compliance and investigators. For example, IRB and Compliance Staff have already identified a faculty member with considerable IRB experience who is willing to serve as chair of a dedicated IRB for student research. With regard to resource needs, the research/academic unit(s) for whom a need is being met may need to be partners in finding the resources needed to implement the new strategy. For example, research/academic units which require student projects might identify and provide board members with release time to serve on a specialty student-research focused IRB. Moreover, senior graduate students could also be appointed (limited 1 yr terms) and be creatively rewarded for their service (for example, teaching stipend or research credit). The Task Force believes that the inclusion of graduate students in IRB board member training and committee functions will provide an invaluable opportunity for the student's professional development and that the addition of qualified student members will add much needed capacity to the system.

For many innovative strategies, resources may be provided as a component of the overhead generated on funded research projects. For others, it might be a budgeted line within a research

program (e.g. clinical trials). Even with some allocation of resources needed to research-intensive departments, it is clear that the university needs to provide the appropriate and consistent level of budgetary resources needed for an exemplary and efficient IRB and Compliance system.

6 REDEFINE THE SCOPE, CONTENT AND FLEXIBILITY OF TRAINING IN HUMAN SUBJECTS PROTECTIONS AND REGULATORY COMPLIANCE

Current training programs in human subjects' protections, IRB processes, and regulatory compliance, do not always reach the investigators most in need of the education. Refining the scope and content of IRB and compliance training, and improving the quality and usefulness of the training will go a long way to improving the general knowledge of the rules and regulations. The Task Force believes that there needs to be more focus on how to effectively deliver professional development and training to each stakeholder group.

Note: the recent implementation of the IRB consulting office hours on campus is an exemplar for a practice that is accessible, convenient, and one that builds new capacity in the system.

6.1 Targeted education

Targeted education needs to reach those most in need. Using feedback from within the IRB and Compliance to identify common errors and/or problematic research/academic units, it is possible to develop high impact, targeted education that will prevent recurrence of common problems, or alter behavior within a research/academic unit. This allows the allocation of scarce training resources to the highest impact areas.

6.1.1 Accountability

Investigators must be held accountable for their knowledge [or lack thereof]. It is fundamental that the individual who indicates to the IRB that they take responsibility for a research protocol understand that they will be held accountable for that protocol, regardless of whether it is a student project or a clinical trial. Core to a regulatory environment is that institutional authorities identify and implement the best means to remediate conditions that are identified as recurring issues in research protocols. Targeted education is a readily available approach to providing timely remediation.

6.2 Content customization

The content of educational modules needs to be customized to the audience for which it is intended. Education for a student in the social and behavioral sciences might focus on very different aspects of human subjects' protections than education for faculty in the College of Business, or for an experienced research coordinator running a clinical trial. The educational focus should be shifted from generalized education to modules customized to the research context of the investigator.

6.3 Student education

Any instructor that expects human subjects research to be done as a component of their courses should recognize the significant workload this places on the IRB and should be prepared to be accountable for his or her students' research protocol and work with the IRB to minimize the impact of the course requirements on general research being conducted within the institution.

Any course for which research is expected should include a module on human subjects' protections and the IRB. The responsibility for providing this education should fall to the course instructor. However, the IRB Outreach staff person(s) should be readily available and resourced to provide classroom, online, and in person education for student research activities.

6.4 Implementation

A shift in the scope, content and flexibility of IRB compliance education requires investment in time and effort for educators, both for course content development and for delivery. However, the institution of an IRB advocate program could offer access to contextualized education within a research/academic unit. Further, easy access to content and answers via electronic solutions will reduce the number and scope of targeted educational needs, relieving the burden of developing and delivering formal educational modules.

Selected Readings

- 2006 AAUP report (<http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm>) on human subjects research and academic freedom
- Report from the interagency committee that oversees the Common Rule, directed the creation of the NSF FAQs (<http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>)
- Mission Creep white paper (<http://qix.sagepub.com/cgi/content/abstract/13/5/617>)
- Report of the IRB Working Group For Research in the Social and Behavioral Science, June 2007, Ohio State University
- The NSF site is particularly rich. For example, there is an exemption category that is particularly informative for K-12 educational research involving standard educational test data sets:

Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior, unless subjects are identified and disclosure of responses would involve more than reasonable risk. (§ 101 (b) (2))