

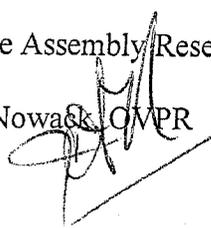


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JUN 16 2006

To: University of Michigan Senate Assembly/Research Policy Committee

From:  James Shayman and  Judy Nowask, OVPR

Date: June 5, 2006

Re: Review and recommendations on the burden of human subjects research regulation.

Dear Committee Members:

We have read the issue memo provided by your group on the burden of human subjects research regulation. We are grateful for the thoughtful analysis provided by your group on the complex and difficult issues surrounding human subjects research. As you correctly note, the federal regulations concerning human subjects research are complex and interpretations are continuously changing. The challenges of protecting human subjects used in University of Michigan research, complying with federal regulations, and meeting the needs of the University research community are significant. These challenges are amplified by the scope of our research programs, which span the entire range of human subjects research.

As a result of your thoughtful analysis, six recommendations were outlined by your group. Many of these recommendations have already been the focus of the IRB Council and OVPR.

Allocation of resources: Recommendations are for an increase in the committee membership, IRB staff, and education for faculty investigators. Committee membership is often limited by the availability of faculty and their willingness to serve. The OVPR has worked, and continues to work, with various deans, department chairs, and institute directors to identify competent, motivated and experienced faculty to serve on the IRBs. The OVPR is committed to the identification of suitable faculty members and is assisting the IRB directors and committee chairs in this process.

IRB staffing is evaluated annually under the budget process. The assessment of operations and staffing needs is also under evaluation through a business model termed LEAN analysis, which has already begun for IRB med. Determining a suitable level of staffing is complicated by at least two factors. First, the University has been transitioning to eResearch. Significant modifications in the design of eResearch continue. While the transition to eResearch has resulted in an increase in short term demands on the IRB staff, when fully implemented we hope to achieve a more efficient process. eResearch will certainly change the kinds of tasks required by IRB staff. Second, the metrics that permit

suitable evaluation of the staffing needs, including workload, turnaround time, and staff/investigator interactions, are currently limited. With the initiation of eResearch, this database is growing and is already resulting in significant changes. For example, we discovered that the time to determination of exempt status of protocols going to IRB behavioral science was significantly longer than for the other IRBs. We determined that this was due to a protocol for this IRB in which faculty committee members were making this determination. We immediately changed the procedures to permit trained senior IRB staff to make this determination. A QA program mechanism will be used to assess the appropriateness of this change.

Education is a significant role of the IRB staff. With the assistance of ISR, we are preparing a systematic education needs analysis that will assist in determining empirically what kinds of education are required by various investigator sub-communities and what the most effective sources of, and venues for, this education would be. We anticipate the evolution of a multi-faceted educational program with the IRB, surely, continuing to play a role. Exactly what that role will be remains to be determined.

Increase faculty compensation and service credit for IRB participation: We hope and anticipate that streamlining will result in a more manageable workload for IRB faculty members. Current streamlining efforts include changes to eResearch, the reevaluation of risk to human subjects, and the identification of research tools (e.g. public databases, well established psychological instruments) that may be subject to pro forma approval.

IRB chairs and those faculty members performing expedited reviews are currently compensated. The level of compensation is equivalent to, and often exceeds, that of faculty members receiving administrative differentials for other comparable activities. Whilst we agree that faculty service commitments need to be considered in the context of the effort expended, we believe that such an evaluation is within the purview of the respective deans, department chairs, or institute directors and not of the OVPR. Establishing general rules to be applied across the University would be difficult and invariably not account for factors such as rank and time in rank, research experience, teaching load, funded effort, and salary. In addition, there is currently no University wide standard for what constitutes appropriate service.

Evaluation of faculty experiences with current IRB processes: This past year OVPR initiated, with the assistance of the ISR Survey Research Center, the development of an ongoing survey instrument for faculty investigators. The continuation of this effort has now been delegated to Ron Maio and his staff at the Office for Human Research Compliance Review. We expect the first survey to be conducted this fall, and that subsequent surveys will assist in tracking our progress toward performance goals.

Create a committee on IRBs as part of the CIC: UM was instrumental two years ago in the creation of such a group and UM representatives are deeply involved in a number of initiatives, such as the development of performance and staffing benchmarks, common policy interpretations, and an analysis of difficult issues in research in international

settings. The CIC group has established a direct relationship for continuing communications with the DHHS Office for Human Research Protections.

Review IRB activities with respect to their role: This has been a major focus of the IRB Council, a group charged with developing and refining university policy. This group has significant faculty involvement. The development of a university-wide HRPP Operations Manual in anticipation of accreditation has helped focus deliberations on the proper IRB role. You may recall the policy promulgated last year distinguishing class activities from regulated research, thus removing class activities from IRB jurisdiction. More recently, a policy removing public data sets has been established in conjunction with a process for continually reviewing data sets that might be added to the list. We anticipate new policy interpretation by OHRP on IRB jurisdiction over release of data from repositories or registries that may have significant implications for UM investigators. In anticipation of the formal release of the new interpretation, we have begun to analyze the changes in university policy on IRB review that might be available.