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FROM: Mary N. Haan, Chair, on behalf of the University of Michigan Senate Assembly Research Policy Committee

RE: Review and Recommendations on Burden of Human Subjects Research Regulation

DATE: May 6, 2006

BACKGROUND

Changes in federal policies governing research have had a significant impact on conduct of research in human. A report from the General Accounting Office[1] suggested that implementation of HIPAA, while primarily intended to protect patients' privacy, had significant impacts on the conduct and costs of doing research with humans. National organizations[2] representing the scientific community have begun to evaluate from a cost:benefit perspective the effects of these changes on human research with respect to (a) documented evidence of improvements in human subjects' protection and (b) increased burden on research activities that might reduce research productivity without improving protections. Other educational institutions have undertaken thorough reviews of human subjects 'mission creep' (expansion of IRB role and scope) [3], responding to faculty concerns about IRB. A recent publication authored by UM OVPR/General Counsel[4] reviewed the impact of HIPAA on clinical research and reported a summary of evidence that the regulations and their implementation by IRBs are adversely impacting the conduct of research without a commensurate increase in protection of human subjects.

Work of Research Policy Committee

The Research Policy committee (RPC) identified this topic as of concern to all faculty doing human subjects research and the review was initiated by the committee as part of its function to represent faculty concerns. Provost Paul Courant also requested this review based on widespread faculty comments to his office about IRB issues.
In 2004-2006, the Research Policy committee undertook to review the effects of new human subjects' regulation on faculty research. This took place in a national context

of increasing regulation of research by the federal government which has translated into more requirements for conduct of human subjects' research at the University level. In addition to interviewing staff and faculty, RPC reviewed other reports on the problem developed by the University of Illinois and University of California Assembly of the Academic Senate. The RPC interviewed representatives from OVPR, the Office of Research Compliance and Review and from IRB Med, Health and Behavioral Sciences Human Subjects' Committees regarding these general issues. Several presentations were made by OVPR staff regarding the current and planned frameworks for managing protection regulation of research involving human subjects. The Table shows those interviewed, the topics and a brief summary of the content.

Electronic management of applications

A very complete picture was obtained of the OVPR e-Research system and plans for facilitating IRB applications. An updated system is now in place and is undergoing evaluation and gradual implementation. The package apparently could include data collection that would be helpful to evaluate faculty experience with the system.

Processing

An additional concern that the RPC addressed was processing time and multiple reviews of applications. Within the IRB Med system, a system of ancillary committees must frequently review applications before coming to the IRB committee. This approach adds to the review time and results in duplicate reviews. At other institutions, ancillary committee members are required to sit on the IRB which shortens the review time. Limited data on this issue were presented to the RPC. During discussion with IRB Chairs from Health/Behav Sci, it was suggested that more information about repeat submissions, extreme processing times, and systematically collected information on faculty experiences would enhance understanding of how to resolve limitations of the current system.

It is recognized that OVPR is developing activities that affect national policies (ie: HIPAA), regional connections and inter-institutional agreements with other Universities.

Resource availability and allocation

Information was provided regarding resource allocation (staff) for IRB Med and IRB Health/BehavSci: IRB Med is staffed at about 26 FTE (of which 3 are designated for faculty education) and IRB Health/Behav Sci has about 6-7 FTE total. The difference in FTE is partly attributed to the number of applications processed by both and to the possibly more complex nature of IRB Med projects. IRB Med operates under the direction of the Dean of the Medical School who reports to OVPR while IRB Health/BehavSci is within OVPR and reports to OVPR directly.

IRB Health/BehavSci may have more departments and more complexity in terms of disciplinary variety than IRB Med. The same IRB Health/BehavSci staff process

applications for both Health (which includes Dental School, Pharmacy and related non Medicine Health Sciences Schools) and BehavSci (which includes all social sciences and related disciplines), so the total number of applications per staff FTE may be similar to or higher than those processed by IRB Med.

The following issues were developed as a consequence of the RPC review:

1. IRB Health/BehavSci resources should be increased to support an investigator education program similar to IRB MED.

2. There should be increases in faculty compensation or release time for chairing IRBs

3. Routine systematic monitoring of faculty and student experience with IRB should be instituted as part of the application process and during annual renewal cycle for all investigators with new or existing protocols. Limitations on student research posed by IRB processing should be evaluated. UM should seek out models of functioning IRB systems to use as examples in revising its current system.

4. Turn around time, repeat submissions of the same protocol, gaps in processing (ie: loss of applications), and other indicators of system performance should be instituted as routine measures and actively used to improve performance.

Recommendations

1. *Allocation of resources*.

An evaluation of resource allocation should be carefully considered with respect to non-MED IRBs. Issues pertaining to this would include the volume of protocols, level of complexity of protocols, degree of organizational complexity (ie: >1 department, subcontracts,etc), time from submission to completion, ratio of applications to staff FTE etc.

 Since the complexity and specialization of knowledge required to understand and develop appropriate protocols has increased, there should be an increase in education for faculty in general, for IRB committee members, staff related to IRB and staff in research projects. IRB MED currently has 3 FTE devoted to this activity. IRB Health/Behav Sci should probably also receive an increase in staff allocations for the purpose of education as well as for processing applications.

 2. *Increases in faculty compensation and service credit for sitting on or chairing IRBs*.

The amount of time required for sitting on an IRB generally exceed the normal 20% expected for service. The amount of time and effort required to manage and chair an IRB committee has also grown. There is an increasing amount of skill and knowledge required for these positions. It is becoming more difficult to recruit faculty to sit on

IRBs and to fill chair positions on IRBs. Although these positions fulfill faculty service requirements, the level of work usually exceeds the 20% normally expected for service activity. The amount and type of service credit or monetary compensation for such positions currently varies widely by department. Committee members are required to undergo training in order to understand and stay current with changing regulations. In addition, extensive scientific knowledge is needed to comprehend the research context of human subject concerns.

Several approaches are possible for addressing this issue: (a) reducing other commitments such as teaching, (b) increasing payment to faculty who chair IRB committees, (c) increasing release time for faculty. Since there is wide variety in current practice at the department and school level, a more consistent policy could be encouraged by the OVPR that would increase interest in participation and forms of compensation (ie: funds, release time, reduction in teaching or other components) for sitting on and chairing committees. Such release time/reduction could include time for additional, ongoing training required for maintaining adequate knowledge of federal regulation on human subjects' research and any local additional regulation and policy. A consistent policy across departments would be desirable since, currently, service credit is highly variable.

3. Evaluation of faculty experiences with current IRB processes.

Currently, there is no consistent practice of evaluating faculty experience with IRB applications other than ad hoc reports from affected (generally disgruntled) faculty. Ad hoc assessment is by nature biased, most probably in favor of those who have had a difficult experience. Routine assessment could be implemented by a brief on-line survey given at the time of the initial application and annual renewal for research protocols. A simple satisfaction rating is probably not informative regarding specific patterns of experience. Such assessment should include the following: (a) average and range of time from submission to completion, (b) number of resubmissions, (c) rating of interactions with IRB staff, (d) delays in starting study protocols (ie: protocol development or data collection) related to IRB processing, (e) specific categorical itemization of reasons for delays and/or disapprovals. An annual report could be generated summarizing these results by unit and by IRB group. This is consistent with the recommendations in the UI White paper. UI concluded that there are few systematic efforts to evaluate these issues through unbiased data collection.

4. A joint Task Force at the Provost level should be established that would include faculty and representatives from OVPR. The mission of this group would be to (a) review the status of IRB functioning and potential 'mission creep' at UM; (b) gather information on how IRBs at other institutions are organized with an intent to select the most optimal functional models for UM; (c) develop recommendations on how systematic assessment of the effectiveness and effects of IRB regarding human subjects research can be done. This TF should include faculty from across campus and be balanced with respect to representation from the School of Medicine, Public Health, other health sciences, social and behavioral sciences.

5. As a member of the CC Big Ten meeting, UM should consider proposing the addition of a committee on IRBs. This would facilitate sharing of information about IRB organizational design, function and effectiveness. There exists a committee devoted to regulatory implementation and audit committees. It is not clear whether this committee also addresses adverse effects on faculty research.

6. A review is needed of IRB activities in defining their role. Some kinds of activities may be appropriately removed from IRB review. IRB currently reserve all decisions regarding potentially exempt research such as analysis of existing de-identified data for themselves. Examples of this are public use datasets (ie: ICPSR) could be classified as not regulated by IRB and would not be considered human subjects research.

Table	Units and person interviewed
Unit/Person	Topic
OVPR: Parnes, Wells	EPRIME research: Design of system and its goals
Office of Research Compliance and Review: John Mather	Discussion of voluntary vs. federal accreditation for human research at the University level.
OVPR: Rob Todd	Medical research regulation/IRB Med organization
OVPR: Judy Nowack	HIPAA certification; IRB plans for operations manuals
OVPR: Nowack, Birk,	Questions asked: How are staffing patterns determined for each IRB and what is their impact on processing? Identified bottlenecks in processing: are these documented? Discussion of possible ongoing evaluation of faculty experience with IRBs that can be fed back to the IRBs to improve service by the IRBs to faculty. Some data presented on time from submission to completion/approval; No data on faculty complaints; potential for increases in work load related to regulatory change
OVPR: Lee Katterman	PEERS system and addition of HIPAA regulations to system
IRB Health/Behav Sci: A. Franzblau, J. O'Shea, C. Kowalski	Discussion of faculty role on committees, compensation, time required for service: resource availability for IRB Health/Behav Sciences