UNIVERSITY OF Miami

FACULTY SENATE

MEMORANDUM

To: Donna E. Shalala
President

From: Stephen Sapp
Chair, Faculty Senate

Stephen Sapp

Date: April 23, 2009

Subject: Faculty Senate Legislation #2008-27(D) – Faculty Senate ad hoc committee on academic freedom report

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At its meeting on April 22, 2009, the Faculty Senate voted unanimously to accept the Faculty Senate ad hoc committee on academic freedom report as presented by Professor Samuel Terilli, committee chair.

The report is enclosed for your reference.

This legislation is now forwarded to you for your information.

SS/rh

Enclosure (Committee report)

cc: Thomas LeBlanc, Executive Vice President and Provost
Samuel Terilli, Chair, Faculty Senate ad hoc committee on academic freedom

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Faculty Senate Legislation #2008-27(D) – Faculty Senate ad hoc committee on academic freedom report

PRESIDENT'S ACKNOWLEDGEMENT OF RECEIPT

RECEIVED: _____ DATE: 4/29/09
(President's Signature)

OFFICE OR INDIVIDUAL TO IMPLEMENT: N. A.

EFFECTIVE DATE OF LEGISLATION: _____
(if other than June 1 next following)

REMARKS: _____

Report of the Faculty Senate's Ad Hoc Committee on Academic Freedom

April 8, 2009

Introduction and Purpose

The Faculty Senate convened this ad hoc committee in 2008 to examine the academic freedom of University of Miami faculty to conduct human subject research. Several faculty members had become concerned about the constraints and delays resulting from process problems in the course of review of human subject research by federally-mandated Institutional Review Boards (IRBs). No member of the Faculty Senate or this committee questions the importance of research productivity, compliance with law, or the protection of human subjects. The question is how to balance those interests in the best possible manner. The members of the committee believe that process improvement and streamlining will better protect human subjects, save administrative costs, and encourage increased research productivity. This report includes an introduction regarding academic freedom generally and the issues that have arisen, a brief review of the applicable federal regulations, and an outline of recommendations for action or at least further consideration.

The Academic Mission

At the University of Miami, we understand that our mission is a broad one. The mission of this academic institution is articulated in a statement that guides its administrators, scholars, employees, students, immediate and extended community, and affiliates in pursuing and satisfying its overarching purposes:

> The University of Miami's mission is to educate and nurture students, to create knowledge, and to provide service to our community and beyond. Committed to excellence and proud of the diversity of our University family, we strive to develop future leaders of our nation and the world. [1]

Our institutional purpose is grounded in the cultivation of students because, without students, our institution could not exist, much less thrive.

This primary mission immediately begs the question with what shall we "educate and nurture" the students. The answer is immediately provided by the second component of the University mission statement, which speaks of creating knowledge. The creators, caretakers, and translators of knowledge are the institutional faculty, whose search for enlightenment through structured and unstructured research represents the framework for information that stimulates learning.

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[1] Mission Statement of the University of Miami available at http://www6.miami.edu/mission/

Because knowledge is an ever-changing resource, institutional scholars must work in an environment that nurtures their efforts. An enriching environment for its scholars is needed for two reasons. First, scholars are attracted, sustained, retained, and cherished by assurances of academic freedom, a search for the common good and its free expression. Second, and on more practical ground, their search for knowledge serves community and institutional imperatives. With respect to the former, knowledge grounded in, but certainly not limited to medicine, science, education, the arts, liberal arts, and humanities, helps the immediate and extended community in which we live, providing service and deriving benefit by improving life quality and quantity while alleviating suffering. Research success also serves the university by providing economic offsets for salaries and indirect costs used to support institutional overhead, including the needed support of its research enterprise. Both logic and enlightened self-interest support freedom to seek knowledge and thus fulfill the intuitional mission of the university.

Research at the University of Miami

The research enterprise at the University of Miami exists in a delicate balance between the altruistic needs and parochial interests of society, the institution, and its scholars. Research pursuits are sometimes conjoined and harmonious, while at other times insular and conflicting. The needs of society must be paramount. Research must be conducted in an environment that shields participants and humanity in general from harm. Where such research is performed it must be conducted under the umbrella of federal law,[2] which promotes a common good and guards against past abuses in human research. This explains the obligation to submit human research in medical, social, and behavioral sciences to ethical authorities, whose mandate is to examine the benefits and risks of the study activities and assure that research participants are effectively informed and protected.

Scholars recognize that a society providing such protections functions on higher ground, but also imposes bureaucratic layers in the conduct of research and the attainment of academic freedom. Thus, pursuit of institutional imperatives, such as creating and sustaining knowledge, can sometimes be frustrated by the systems needed to authorize and oversee institutional research activities, an irony with which we all must live - to a certain degree. Institutional review systems should be organized solely to protect human subjects and not to fulfill bureaucratic policies.

In the best of worlds, administrative entities that oversee the research enterprise would work harmoniously with its users, despite their plurality, parochial interests, and individual missions. Recognizing the primary mission, indeed the raison d'etre, of the IRB to be the protection of human subjects of research and acknowledging that this might, at times, come into conflict with other goals, it is to be hoped that the IRB would pursue its mission in such a way as to assist the scholar in pursuing knowledge. This would be achieved through optimal performance and cost-efficiency, operational

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[2] *See* 45 C.F.R. 46 (2009).

transparency, and established mechanisms that assure fairness and protection to all parties. Operations would be coalesced to minimize the time and paperwork burden of application for research approvals, and of ongoing reporting and study closures.

Some researches and others involved with institutional review boards (IRB) might assume that all questions are answered by the terms of 45 CFR 46, but the regulations are not that specific, nor could they possibly be. This University has itself often recognized in its reports and policy statements the importance of increasing efficiency and fairness to faculty scholars, principles that are not articulated in 45 CFR 36, but are clearly logical and worthwhile.

The IRB is not the only actor in the process of reviewing faculty research. Other research offices with which university faculty interact include the Jackson Memorial IRB, Veterans Administration Medical Center IRB, The General Clinical Research Center, and the Clinical Research Initiation Services (CRIS) Office, all of which maintain separate offices, administrators, staff, paperwork, and procedures. An inspection of their individual tables of organization would be daunting, even for the most seasoned of researchers.

Moreover, there is no central authority to assist researchers in determining whether they are exempt from oversight, no formal mechanism to provide assistance in navigating the often conflicting waters between these units, and no ombudsman to equitably resolve research disputes. Committee members heard from several faculty members in the social sciences who have decided to forego human subject research in the form of surveys as a means of avoiding delays in their work and in publishing. Others expressed concern that their research, be it medical, psychological, or sociological was at times reviewed by individuals who lacked the appropriate background in the relevant fields, or who had interests beyond those required to protect human subjects.

The committee recognizes that some of the concerns may involve misunderstandings by either faculty researchers or reviewers or both and may in fact be far more complicated. This is not a condemnation of any IRB or of the need for institutional review of human subject research covered by the federal regulations. Rather, these concerns reflect, at a minimum, problems of perception regarding the process as well as instances of needless delay and complication. Simply put, for many faculty scholars the research review has become confusing and an impediment to efficiently pursuing knowledge, and by translation, a hindrance to realization of the university mission. No great institution should operate in such a manner or should maintain a review process with such a poor reputation among any faculty. The process and the perception should be addressed.

This articulation of faculty concerns is not intended to suggest that any person, board or office is acting in bad faith or purposely to impede research. Rather, this ad hoc committee, by beginning to examine the process, has concluded that as research has become more complex and diverse the means adopted to protect the public and

comply with the law have also become more complex and diverse. Rather than merely accept this state of affairs as inevitable and insoluble, this ad hoc committee is recommending an examination of these processes to improve them – for the benefit of society as well as the university and its research faculty. To that end, this report sets forth a list of recommendations for further consideration.

The General Question of Academic Freedom and Federal Law

As faculty, we recognize and welcome our obligation to protect the subjects of human research. We also recognize we can best understand that obligation if we also understand the applicable law and regulations. In 1979, the Department of Heath, Education and Welfare (now Health and Human Services) issued the famous Belmont Report, entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research."[3] This report is the place to begin.

The Belmont Report recognized that risk ("a possibility that harm may occur") had to be justified in terms of a benefit assessment ("something of positive value related to health or welfare" and not a mere possibility of benefit).[4] The Belmont Report also noted that while the most likely types of harm that might result from human subject research involved psychological or physical pain and injury, other forms of harm had to be considered:

> Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits.[5]

The Belmont Report's recognition of harms beyond the physical or psychological raises the question whether all human subject research must be reviewed to assess the benefits and potential harms.

The applicable provisions of the Code of Federal Regulations (CFR)[6] fulfill the spirit of the Belmont Report by focusing on a subset of research that may cause the harms identified in the Belmont Report. The federal regulations accomplish this by defining those categories of human subject research that are exempt from coverage of

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[3] The Belmont Report, Office of the Secretary, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Apr. 18 1979; available at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm (retrieved Mar. 17, 2009; the "Belmont Report").

[4] Belmont Report at 8 (Part C: Applications; 2. Assessment of Risks and Benefits/The Nature and Scope of Risks and Benefits).

[5] *Id.* at 8-9.

[6] 45 CFR §46 (2009)

the law – in effect, by carving out the exceptions and leaving the rest under the law's umbrella. For example, research activities in which human subjects are involved only because they participate in an education test, a survey, interview or observation of public behavior are exempt as follows:

> Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.[7]

The question whether an IRB must itself decide which research is exempt and which is not is not addressed directly in the federal regulations, but is answered by the structure of those regulations and the provisions for expedited review. First, there is no provision requiring that an IRB examine all research to determine whether or not it involves humans – the threshold criterion for coverage under the regulations. Second, the regulations provide for expedited review of research, but only if the research falls into a category designated by the Secretary of HHS and if an IRB concludes that the research involves no more than minimal risk or involves only minor changes to previously approved research during the period of approval (if one year or less).[8] Thus, the regulations contemplate two categories of human subject research (i.e., exempt and non-exempt) and two subcategories of non-exempt research (i.e., that which requires a full review and that which is eligible for an expedited review). IRB action is specifically required in terms of both categories of non-exempt research, but not in the case of exempt research.

This approach supports the position that IRB action is not required to determine if research is exempt or not just as IRB action is not required to determine if a particular research proposal involves humans or not. This conclusion is further supported by the regulation governing proposals lacking definite plans for involvement of human subjects.[9] The section of the regulations specifically states that such proposals do not require IRB review and that except for research that is exempt or otherwise waived by HHS, no human subjects may be used until review. The import of this section is that exempt research need not be reviewed.

Any university is, of course, free to adopt and support its own internal rules requiring a wider scope of review than that mandated by federal law, but this course of action carries with it potential risks as well as benefits. The possible benefit is the security that comes by having a board review all research to be sure no research escapes a required review. The possible risks are two-fold. First, research might be needlessly impeded or changed. This is a serious concern because impeding research

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[7] 45 CFR §46.101 (b)(2) (2009).
[8] 45 CFR §46.110 (2009).
[9] 45 CFR §46.118 (2009).

is counter-productive, hurts the university and society and possibly intrudes upon the spirit, if not the letter, of academic freedom. Second, the university by sweeping the net so widely and scooping up clearly exempt research will dilute its resources by focusing on those types of research that are not potential problems (and, thus are exempt) and not spending adequate time on those that are truly matters of concern. No institution has unlimited resources. If there should ever be a problem with covered research that was reviewed, but perhaps not adequately reviewed because time and resources were expended on clearly exempt research, then the university could find that its so-called conservative approach might be used against it and might actually lead to greater risks, legal or otherwise.

A streamlined, effective and efficient review process is in the interests, therefore, of all concerned: the university, the faculty, any subjects of research, and society. In that spirit, this committee has attempted to look at the review process at the University of Miami in a holistic manner. We believe strongly that an effective review process helps the faculty. We also believe that minor adjustments to the process may yield significant benefits.

Recommendations for Further Consideration and Process Improvement

The Ad Hoc Committee offers these recommendations in the spirit of further discussion and exploration. We recognize that some might include problems related to costs or practicability that we cannot assess without additional information. These are set forth, however, because after examining problems that have arisen from time-to-time in different fields, ranging from medical research to communication and behavioral research, we have concluded that some changes are needed to ensure the efficacy of the review process. While all of the recommendations are important, the first three will have the greatest impact if adopted. The recommendations include, in outline form:

1. **Single Administrative Umbrella and Form**:

A.) Single Department: If the IRB, GRCC and CRIS functions reported to a single office or administrator, this might provide for greater coordination.

B.) Single Form: Create a single electronic form for submissions to the IRB, GRCC and CRIS that is user friendly and responsive to the needs of all three (for example, programming the electronic form so that once subparts are hidden once the investigator marks a section as "not applicable" would be helpful).

C.) Recommended Reviewer Expertise Designation: Add to the new form a field for the researcher to recommend particular expertise needed in the review process.

D.) Streamline Attachments to Form: Eliminate needless attachments and allow references to generally available and standard questionnaires, equipment descriptions,

federal regulations, photographs of equipment, standard psychometric questionnaires, etc. Allow references to previously filed attachments in subparts to research proposals.

E.) Do not assume that forms that apply to medical research automatically apply to social science research. Eliminate, perhaps by hiding after check-off electronically, the required fields that do not apply to social science research.

2. **Increased Faculty Representation**:

A.) Ombudsman: Because some issues can be resolved with more communication and clearer lines of communication, appoint a faculty ombudsman for each IRB. This would be a person to whom any faculty member could refer questions or concerns regarding a submission. We recommend that each ombudsman make an annual report to the Faculty Senate.

B.) Liaison: Add a faculty liaison from each department or division to each IRB relevant to that department or division as is currently done by the GRCC. This, combined with making faculty available for consultation with other IRBs will increase the depth and breadth of the expertise available to each IRB.

3. **Clearly Exempt Research**: Some research, though it involves human subjects, is clearly exempt under the federal regulations and applicable law and some faculty are walking away from this work to avoid the complications associated with review. Typically this would include social science or similar research that meets the definition of exempt under the Code of Federal Regulations. If these research proposals can be moved out of the IRB queue, the work of the both the researchers and the IRBs will be expedited. Any proposal that might be exempt, but would be a close call, would still go to the IRB. (as explained above in the text accompanying footnote 7, the federal regulations essentially define exempt research to be educational tests, surveys, interviews and observations that lack any human identifiers and could not reasonably be expected to have any negative consequences for the respondent in terms of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation).

A.) Designate Departmental or School Representative to Review Clearly Exempt Research Proposals: This individual (appointed by the relevant Dean in consultation with the Provost) would receive the research proposal and within five business days either confirm that it is exempt or refer the matter to the appropriate IRB for further consideration.

B.) Train Designative Representative: The person designated above would be trained as required by UM to assure compliance with IRB standards, as IRB chairs are currently trained.

C.) Audit: IRB or designee would periodically audit each representative's records to assure compliance.

4. **IRB Membership**: Because the IRB exists to protect human subjects and is not a legal risk reduction body, and because these two functions might at times conflict, we recommend removing university legal counsel from IRBs and allowing for post-IRB legal review of any relevant research proposals.

5. **Additional Training**: We recommend additional training opportunities for faculty, particularly new faculty, as well as graduate students with regard to IRB processes and compliance. In addition, we recommend the ombudsmen participate in this training.

Conclusion:

Human subjects must be protected. Students must be educated. The University must serve society as well as it students. Effective research and effective institutional reviews of human subject research are essential to all of those goals. The Ad Hoc Committee concludes that the University of Miami has in place a system of research review and related services that operates in good faith and with a desire to protect and serve. However, with time, increasing specialization of research and the addition of new faculty with diverse research interests, the existing process for review has become dysfunctional and in need of a new examination and adjustment. The recommendations set forth above will require additional discussion, but the ad hoc committee believes the effort will be worthwhile because it will ultimately enhance research productivity, protect human subjects more thoroughly, and serve our students and all of society.

Members of the Ad Hoc Committee on Academic Freedom: Linda Liska Belgrave; Mary Ann Fletcher; Mark Nash; Thomas Steinfatt; and, Samuel Terilli (chair)