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INFORMED CONSENT AND ACADEMIC FREEDOM

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It is a fundamental tenet of the philosophical discipline of ethics that nobody's rights are absolute. Inevitably, situations occur when a right claimed by one group clashes with a right claimed by some other. An example of such a potential incongruity is "Academic Freedom vs Informed Consent" and one mechanism that has been developed to seek balance between this set of rights is the "Institutional Review Board." When a conflict in this domain arises, it most commonly pits faculty researchers (academic freedom) vs. the IRB (protection of human subjects).

Academic Freedom is the touchstone of a university of quality. The Faculty Policy Manual of NSU contains a definition of Academic Freedom which includes the following declaration: "Teachers are entitled to *full freedom* (emphasis added) in research and the publication of the results..." This is a very powerful statement with far-reaching implications. At the very least, it promotes intellectual diversity in the faculty.

Genuine violations of a faculty member's academic freedom are rather rare, and if one takes place, the offended faculty can file a grievance for redress of this violation. It is not a difficult task to identify the perpetrator; there is no way to conceal the violation, because somebody had to direct the offended faculty to cease some specific line of research."

A faculty member would not rationally observe a restriction that was identified only by an unsigned anonymous directive unless it came from the Institutional Review Board (IRB).

Anybody who makes a criticism of a particular research protocol can be identified

and debated unless they speak as a member of an IRB. A critic who attacks a particular project based on illegitimate motives or just plain incompetence can be identified and subjected to a grievance procedure unless he speaks as a member of the IRB.

Institutional Review Boards were initially generated to preclude the abuse of human subjects in various experiments. This is a very important function which bears upon both the experimental subjects and the faculty seeking approval for a project or experiment.

But who monitors the IRB?

Nobody!

Who determines the qualifications for membership on an IRB?

Nobody!

To whom does an IRB report?

Nobody! (Nobody, that is, except the various supplicants for approval.)

Institutional Review Boards are in an ironic position: they must apply rules to other faculty but are not, themselves, similarly monitored. IRB members seek anonymity as protection from retaliation, but this simultaneously creates an atmosphere which invites abuse.

The fundamental purpose of any IRB, including NSU's, is the protection of human subjects, not the approval of research protocols that have little potential for harm.

How can we simultaneously protect patient's rights without restraints on Academic Freedom?

First, membership on an IRB should not be a "crap shoot." There is already a federal requirement that an IRB must have one lay person who has no connection with the university. A clear majority of the rest of the membership should have had direct personal experience with research on human subjects.

Second, the general protocol by which the IRB deals with each project should be published and distributed to all faculty. This would not include the publication of details of the proposed research, which are protected as intellectual property of the researcher.

Third, when an application is rejected, the reasons for this decision should be explained, in writing, to the applicant. The applicant should also receive concrete suggestions by which he can gain approval for a project. It should be an obligation of the IRB to provide this "feedback" in a timely manner.

Fourth, decisions rendered by an IRB have a profound influence on faculty who submit projects for approval. The faculty member operates on a specific time-line, the IRB does not. While it may be convenient and efficient for an IRB to schedule regular meetings on, say, a monthly basis, there should also be a provision for "between-meeting accelerated review" where minimal risk is involved. This could take the form of a review by the chair of the IRB who would then make a report at the next scheduled meeting of the full board.

HPD RESEARCH APPROVALS MAY 2009

College of	Investigator	Protocol Title	Sponsor	Amount
Allied Health and Nursing	Ann M. Lucado	Characteristics of the Upper Extremity in Female Recreational Tennis Players with and Without Lateral Epicondylagia	NSU-HPD	\$5,578.20 For two years
Dental Medicine	Dong Kyung Kim	Pressure Analysis in the Distal Extension Areas in Implant-Supported Removable Partial Dentures (ISRPD)	NSU-HPD	\$5,000.00 For two years
Optometry	Rachel A. (Stacey) Coulter	NSU Convergence Insufficiency Treatment Trial Reading Study (CITT-RS): Effectiveness of Office-Based Vergence/Accommodative Therapy for Improving Reading Performance in Children with Symptomatic Convergence	NSU-HPD	\$5,000.00 For two years
Osteopathic Medicine	Patrick C. Hardigan	Comparison of Ultrasound-Guided to Landmark-Guided Femoral Artery and Vein Access in Adult Cardiac Catheterization	NSU-HPD	\$2,100.00 For one year

HPD RESEARCH APPROVALS JUNE 2009

College of	Investigator	Protocol Title	Sponsor	Amount
Allied Health and Nursing	Sarah Ransdell	The Features of Multimedia Instruction that Promote Meaningful Distance Learning	N/A	N/A
Dental Medicine	Umadevi Kandalam	In Vitro Cell Proliferation and Osteogenic Differentiation of Postnatal Stem Cells	NSU-HPD	\$5,000.00 For two years
Dental Medicine	Richard H. Singer	A Comparison of Analog and Digital Cephalometric Analysis-Overall and Regional Super-Impositions	NSU-HPD	\$5,000.00 For two years
Dental Medicine	Vincent Van	Failure Strength of Four Veneered Primary Posterior Stainless Steel Crowns	NSU-HPD	\$5,000.00 For two years
Pharmacy	Hamid Omidian	Novel Expandable Platforms for Gastric Retention	NIH & NSF	\$10,000.00 For one year

HPD RESEARCH APPROVALS JULY 2009

College of	Investigator	Protocol Title	Sponsor	Amount
Dental Medicine	Philip Simon	Micro-Computed Tomography Analysis of Root Canal Fillings Using ThermaFil and RealSeal Core-Carrier Obturators	NSU-HPD	\$5,000.00 For two years
Pharmacy	Sri Rama Krishnaiah Yellela	Penetration Enhancing Effect of Geraniol and Fenchone on Transdermal Pemeation of Flurbiprofen	NSU-HPD	\$5,000.00 For two years

QUOTABLE QUOTES

"Searching is half the fun: life is much more manageable when thought of as a scavenger hunt as opposed to a surprise party."
Jimmy Buffett

"You can tell whether a man is clever by his answers. You can tell whether a man is wise by his questions."
Naguib Mahfouz