In this Issue . . .

In the last issue of *Focus on Research* we printed a guest editorial by Paul Abplanalp, O.D., Ph.D. The editorial raised questions concerning the IRB as it relates to oversight, academic freedom, timeliness, and responsiveness.

In this issue the current Chair of the IRB, Dr. Teri A. Hamill, will respond to the editorial.

Please note that the views expressed by Dr. Abplanalp and others do not necessarily reflect those of the *Focus on Research* editors.

The Office of Research in the Health Professions Division provides support for the faculty and staff of the Health Professions Division in their efforts to obtain and conduct research, while ensuring compliance with NSU policy, sponsor policy, and applicable law.

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The Role of the IRB

Teri A Hamill, PhD,
Chair, Institutional Review Board

An opinion piece on academic freedom and the Institutional Review Board (IRB) ran in the July newsletter. I appreciate this opportunity to provide information about the NSU IRB, to clarify some of the misinformation that was presented, and to answer the questions posed by the author.

As health professionals and educators, we are used to the freedom to act within the scope of our professional licenses, and to apply the teaching methods we think best. Conducting or ordering diagnostic procedures, deciding on patient management, conducting or facilitating treatment all occur ostensibly without oversight. However, we use FDA-approved instruments and treatments, and the teaching methods we employ spring from tradition and research. When a clinician seeks to create new knowledge, to tackle important health-related research questions, or to compare the efficacy of known treatments rather than limit oneself to patient care, then he or she is required to obtain prior approval for the research from the IRB.

Let me take a moment to address some of the specific questions posed in last month's newsletter. I will paraphrase and answer them.

Why have an IRB?

Federal law requires each institution that receives federal dollars to conduct research to have an IRB prospectively review research involving human subjects, and to apply federal regulations that protect the welfare of research subjects. Society has spoken through its elected officials. NSU applies the rules protecting human subjects to all human subjects research, irrespective of funding source. The tradition of protecting human subjects via IRBs is 30 years old. It is not a perfect system; anyone who works with IRBs will attest to that!

A critical part of the IRB process is that the researcher presents his/her study proposal to his/her peers for review, so that the peers share responsibility for the protection of human subjects. Together, the researcher and the IRB work to determine that the risks have been correctly identified, and that study procedures minimize risks and maximize benefits. They ensure that the mechanism of informed consent permits subjects to express their autonomy in deciding whether to participate, and they work to make sure that the potential research participants clearly understand the research, its risks, and benefits.

Who comprises the NSU IRB?

The NSU IRB is a body of your peers. Each center has a member and at least one alternate member, each nominated by the center dean, and appointed by the Vice President for Research and Technology Transfer. Members serve three year, renewable terms. Our IRB has three non-affiliated community members who serve as public advocates. The members of the Board elect the Chair. Neither members nor the Chair receives any additional stipend.

The IRB has only two full-time staff members: an administrator (Dr. Jaime Arango) who answers researcher questions, assists researchers as needed, communicates with IRBs at other institutions, and oversees the operations of the Board, and one clerical staff person (Ms. Inga Hess) who processes the received submissions, sends out communications, and maintains the IRB's records.

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What determines the level of review?

The federal Common Rule (45 CFR 46), the guidance documents provided by the Office for Human Research Protections (OHRP), which is a part of the Department of Health and Human Services, and when applicable regulations promulgated by the Food and Drug Administration (FDA), stipulate how studies are reviewed. The risks that a study poses, the vulnerability of the subjects, the methods proposed by the researcher, and the types of data collected affect the level of review that a research study requires. Information about the process is available on the IRB Web site, from your college representative, from Dr. Arango, and from me.

Who monitors the IRB?

Just about everyone! University professors, not being shrinking-violet personality types, regularly challenge the decisions of the IRB. While the Board must be autonomous so that the financial benefits to researchers' departments and the university cannot unduly influence the Board's decisions about human subjects protections, the policies and procedures that the Board operates under are approved by the Vice President for Research and Technology Transfer. As discussed above, the IRB does not apply arbitrary standards: its job is to apply concrete federal and state regulations as these govern researchers as much as they govern IRBs.

Why doesn't the IRB publish and distribute the procedures that it uses?

Both OHRP and the FDA require that the IRB have procedures that are written and accessible. They are published on the IRB Web site.. The NSU IRB approved, via differing levels of review, 756 protocols last year, indicative of the accessibility of the NSU IRB's forms, policies, and procedures. Visit www.nova.edu/irb

Why are reviewers anonymous – because they don't want retaliation, right?

The members are listed on the IRB Web site. Researchers know who their center representative to the IRB is, because the research proposal is submitted initially to the center representative. The reviewers are hardly anonymous. However, decisions made at a convened meeting of the Board are passed by majority vote; the individual member's votes in favor or in opposition are not recorded.

Why aren't the majority of the IRB members persons with scientific background?

Under the Common Rule, at least one member must have a scientific background and one member whose expertise is in a non-scientific areas. Tradition at NSU dictates that there are more individuals with scientific training and experience than not.

There should be provisions for review between monthly meetings.

There are. If the study falls within one of six federally-defined categories of minimal risk (not greater than the risks in everyday life) studies that are exempt from further IRB review, then the study can be reviewed just by the center representative. Last year, 596 of 756 research studies received this level of review. The IRB chair rather than the full Board reviews other minimal risk studies (via a procedure called "expedited review") that fit within one of nine other federally defined categories. This review level was used in 20% of the studies last year; therefore, only 1.3% received full board review.

When an IRB proposal is rejected, why aren't researchers given feedback?

Research at NSU is seldom rejected, but when changes are requested so that the study, in the opinion of the reviewer(s), meets federal requirements, researchers are given feedback. Sometimes we hear complaints that the feedback is too extensive. A recent full board review resulted in a 6 page compilation of areas of concern to be addressed. Expedited review memos can be just a few bulleted items, or may run several pages in length. If the study being reviewed under expedited procedures needs more modifications than could be dealt with in a few pages of comments, the study is returned to the investigator who is asked to work with the center representative before resubmitting. If a study is disapproved, which incidentally can only be done at a convened meeting of the Board, the federal regulations and the NSU IRB's policies require that the researcher be told exactly the reason why the study was not approvable. If anything, individuals who have submitted to the NSU IRB know that they often get much more feedback than they would like to receive!

Why isn't feedback given in a timely manner?!

Center representatives are typically not given any release time for their work with the IRB and they are not paid a stipend of any sort. The time that it takes a center representative to review a study can vary. If you do not receive feedback as to the status of your study within about two weeks of submission to your center representative, talk with the representative. Perhaps an alternate representative could review the study. If timeliness is still a problem, alert the IRB administrator, Dr. Jaime Arango (2-5311). Dr. Arango is also available to answer questions on the IRB process and suggest solutions if one is not sure how to make changes to meet NSU / federal requirements.

The average turnaround time for expedited review feedback at NSU is just under three days, while nationally expedited reviews can take up to 45 days. This includes time to scan the documents, create the file, review the protocol, and process the memo that is sent out to the investigators, and is in part limited by the fact that we only have one FTE of clerical staff, Ms. Inga Hess. Considering that the IRB has just two FTE plus the chair's release time of 0.2 FTE, I think we do a commendable job of processing submissions in a timely manner.

When the full Board reviews a study, it will take a little longer to receive formal feedback. If the center representative was present at the full board meeting, the center representative can give the researcher informal feedback immediately. The minutes of the discussion have to be completed to ensure that the letter to the investigator(s) contains all relevant information, so it can take a week for researchers to receive formal notification. In rare cases, it has taken a little longer than this when the Chair's other academic responsibilities conflict with IRB responsibilities, and when the day refuses to lengthen beyond 24 hours.

Doesn't the IRB Infringe on Academic Freedom?

The IRB respects and is committed to preserving academic freedom. Federal law requires that we review research protocols that propose human subject research, but we do so for limited purposes – to ensure risk to subjects is minimized

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and is appropriate in light of potential benefits, to ensure when possible their equitable selection, that informed consent will be sought from each prospective subject and will be appropriately documented, and when appropriate that the research plan makes provision for data monitoring for the safety of subjects, and to ensure the privacy of subjects and the confidentiality of their data (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111). We strive not to intrude into academic freedom or seek to impose our individual values on researchers. When we seek additional information, we do so to further the mandates imposed by federal law.

I will end with a question of our own.

Have you considered volunteering to be on the IRB?

Why would one want to take on this job? Because it is interesting to see the research studies conducted at NSU, because it is interesting to take a different role – to be asked to see things from the subject's perspective and from a regulatory perspective. Tell your center representative and/or your Dean if you are open to being appointed to the IRB as either the representative or an alternate.

Please note that if your center needs additional information on the IRB process, the administrator, chair, and vice-chair all can help. Likewise, the center representative is also a good person to contact if you have a class that could benefit from hearing about the IRB process.

Closing Comments

As a reader of the last newsletter would probably have surmised, being on the IRB is not a popular job. The perception of some is that the IRB is intent upon restricting academic freedom. To the contrary, if it were not for the volunteer efforts of the IRB members, human subjects research could not be conducted at NSU. A benefit to being on the IRB is the opportunity to learn about the research conducted here, and to learn from one's colleagues. The Board is comprised of some of the most diligent and caring members of the NSU community. The debates are thoughtful and respectful, and reflect the commitment of each member to their primary role: the protection of the human subject.

Last, the issue of academic freedom does deserve some discussion. There are reasons why IRB reviews may conflict with academic freedom. It is an issue that has come up at Board meetings when the IRB struggles between asking for changes that may maximize benefit and respecting the rights of the investigator to conduct research in his or her chosen field of expertise, with his or her chosen methods. I hope that thoughtful exchanges on how to best balance these conflicting values will continue.

Next issue FOR in January 2010

INTERNAL RESEARCH GRANTS FOR APRIL 2009				
COLLEGE	INVESTIGATOR	PROTOCOL TITLE	SPONSOR	AMOUNT
Dental Medicine	Pavel Ivanov	The Effect of Rapid Palatal Expansion on the Anteroposterior Position of the Maxilla and Mandible	NSU-HPD	$1,400.00 For one year
	Ana Maria Gallego	Novel Use of Botox as an Adjunct to Cleft Lip Reconstruction	NSU-HPD	$2,500.00 For one year
INTERNAL RESEARCH GRANTS FOR MAY 2009				
COLLEGE	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

INTERNAL RESEARCH GRANTS FOR JUNE 2009

COLLEGE	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
	Hamid Omidian	Novel Expandable Platforms for Gastric Retention	NIH & NSF	$10,000.00 For one year
	Richard H. Singer	A Comparison of Analog and Digital Cephalometric Analysis-Overall and Regional Super-Impositions	NSU-HPD	$5,000.00 For two years
	Vincent Van	Failure Strength of Four Veneered Primary Posterior Stainless Steel Crowns	NSU-HPD	$5,000.00 For two years

INTERNAL RESEARCH GRANTS FOR JULY 2009

COLLEGE	INVESTIGATOR	PROTOCOL TITLE	SPONSOR	AMOUNT
Dental Medicine	Trina Buchal	An In-Vitro Evaluation of the Release of Silver Ions from OrthoShield Safe-T-Tie Orthodontic Ligatures Over a 30-Day Period	NSU-HPD	$2,690.00 For one year
	Phillip 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 Permeation of Flurbiprofen	NSU-HPD	$5,000.00 For two years

INTERNAL RESEARCH GRANTS FOR AUGUST 2009

COLLEGE	INVESTIGATOR	PROTOCOL TITLE	SPONSOR	AMOUNT
Allied Health and Nursing	Ming-Shun Cheng	Mechanism of Shoulder Wii-it is with Wii Tennis a Biomechanical and EMG Analysis	N/A	N/A
	Madeleine A. Hellman	Balance and Ambulation Training Without Standing Upright	N/A	N/A
Optometry	Bai-Chuan Jiang	The Objective Visual Performance of the Human Eye with Different Contact Lenses	NSU-HPD	$657.00 For one year

INTERNAL RESEARCH GRANTS FOR SEPTEMBER 2009

COLLEGE	INVESTIGATOR	PROTOCOL TITLE	SPONSOR	AMOUNT
Dental Medicine	Jonathan Madras	The Effects of Multiple Cycles of Use and Sterilization on Nickel-Titanium Rotary Files: EndoSequence, RaCe, Twisted Files, and K3	NSU-HPD	$5,000.00 For two years
	Peter E. Murray	NSU's Biocompatibility Screening Alternatives to Animal Experimentation	PFRDG	$10,000.00 For one year
	Prathima Paleti	Comparison of Transverse Skeletal and Dental Arch Width Changes Among Orthodontically Untreated Caucasians	NSU-HPD	$3,650.00 For one year
	Tamara K. Robison	Screening, Counseling, and Referral of Pregnant Women to Prevent Early Childhood Caries: A Survey of Obstetricians on Oral Health Assessments and Collaboration with Dental Providers	NSU-HPD	$4,050.00 For two years
	Marjan Salari	Physical Properties (Roughness, Hardness, Gloss and Color Stability) of Four Provisional Cements for Provisional Restoration	NSU-HPD	$2,500.00 For one year