Poster Abstracts from the 2004 IRB Conference: Communication: The Cornerstone of an Ethical Research Environment

October 27-29, 2002

San Diego, California
<table>
<thead>
<tr>
<th>Abstract</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Structured Review System Prior to IRB Discussion</td>
<td>4</td>
</tr>
<tr>
<td>Assessment of Vulnerability and Risk: IRB Attitudes Toward Medical and Psychiatric Patients</td>
<td>5</td>
</tr>
<tr>
<td>Bridging the Gap: Improving Communication between the Institutional Review Board and the Research Community</td>
<td>6</td>
</tr>
<tr>
<td>Children's Oncology Group Central IRB Survey</td>
<td>7</td>
</tr>
<tr>
<td>Communicating with Students as They Navigate the Human Subjects Approval Process</td>
<td>10</td>
</tr>
<tr>
<td>A Computer Based Learning Program to Teach Non-Research Clinical Staff About Clinical Research Data Collection</td>
<td>11</td>
</tr>
<tr>
<td>Continuous Quality Improvement Program</td>
<td>12</td>
</tr>
<tr>
<td>Does a Signed Informed Consent Form Assure Informed Consent?</td>
<td>15</td>
</tr>
<tr>
<td>Educating Promotores on Ethical Practices and Principles to Enhance Human Subjects Protections</td>
<td>16</td>
</tr>
<tr>
<td>Electronic Submission of Unanticipated Problems</td>
<td>17</td>
</tr>
<tr>
<td>Evaluating the Readability of Pediatric Research Consent Forms</td>
<td>18</td>
</tr>
<tr>
<td>Framework For Discussing And Resolving Ethical Issues In The Clinical Research Setting</td>
<td>19</td>
</tr>
<tr>
<td>How Often do Clinical Studies Meet their Enrollment Goals?</td>
<td>20</td>
</tr>
<tr>
<td>Improving IRB Review and Response Time</td>
<td>22</td>
</tr>
<tr>
<td>Investigator's Perceptions of Communication from the IRB: How adequately do we convey respect and beneficence?</td>
<td>24</td>
</tr>
<tr>
<td>IRB Guidance on Pediatric Research: What is Helpful or Problematic</td>
<td>25</td>
</tr>
<tr>
<td>Institutional Review Board Turn Around Time</td>
<td>26</td>
</tr>
<tr>
<td>IRBNet: The Networked IRB</td>
<td>27</td>
</tr>
<tr>
<td>Launching the IRB into Cyberspace: e-Enabling Board Review Near and Far</td>
<td>29</td>
</tr>
<tr>
<td>Medical Schools’ Attitudes and Perceptions Regarding the Use of Central Institutional Review Boards (IRBs)</td>
<td>30</td>
</tr>
<tr>
<td>Necessary Elements in Fundamentals of Human Studies Research</td>
<td>31</td>
</tr>
<tr>
<td>Not For Cause Review Program</td>
<td>32</td>
</tr>
<tr>
<td>OCREEB: A central research ethics board for cancer</td>
<td>34</td>
</tr>
<tr>
<td>Parental Understanding of HIPAA in the Emergency Department</td>
<td>35</td>
</tr>
<tr>
<td>Patient's Consent for Donating Leftover Tissues in Singapore</td>
<td>37</td>
</tr>
<tr>
<td>Primary Reviewer Assignment and its Impact on IRB Approval: Experience at One Medical Center</td>
<td>38</td>
</tr>
<tr>
<td>Protecting Human Research Subjects in the NIH's Intramural Research Program: A Draft Instrument to Evaluate IRB Performance in Convened Meetings</td>
<td>39</td>
</tr>
<tr>
<td>A Program to Enhance the Protection of Research Subjects in Zimbabwe</td>
<td>40</td>
</tr>
<tr>
<td>QA/QI of the Informed Consent Process Using Patient Satisfaction Surveys</td>
<td>41</td>
</tr>
<tr>
<td>Recruiting IRB Committee Members</td>
<td>42</td>
</tr>
<tr>
<td>Setting up an IRB in a Developing Country- The NMIMR Experience</td>
<td>43</td>
</tr>
<tr>
<td>A Survey of Clinical Research Investigators and Clinical Research Coordinators About the Process of Informed Consent</td>
<td>44</td>
</tr>
<tr>
<td>The IRB Role in Protecting Human Embryos Created Through In Vitro Fertilization</td>
<td>45</td>
</tr>
<tr>
<td>The Nonscientist's Review Process of a Biomedical Protocol</td>
<td>46</td>
</tr>
</tbody>
</table>
A Structured Review System Prior to IRB Discussion
Authors: Mira D. Shah, CIM; Martha J. Matza, MS

Background
The structured review process initiated several years ago at U.T. M.D. Anderson Cancer Center has proven to be a unique and valuable program. All clinical and behavioral science protocols undergo an intense peer review before being presented to the Institutional Review Board (IRB). During a one-year cycle of submitted protocols, the M.D. Anderson IRB received 840 human subjects research protocols for review. During that time, 308 protocols were presented for review to the full IRB committee. Of these, 291 were approved. The average time for a protocol, from submission to IRB approval, was 35 days with a median time of 25 days, and a range of 16 to 271 days. These protocols were managed using a detailed structured review process.

Designated Focused Review:
Authorized reviewers are selected from faculty members according to their areas of expertise. Two focused reviewers are assigned a newly submitted protocol to critique. The first reviewer selected is chosen from a list of investigators who submitted new research project protocols during the selected review cycle. This is what is referred to as the "submit one review one" choice. The second reviewer is matched to the protocol for review by the corresponding area of disease that has been authorized by the institution’s division and department leadership.

Supplemental Reviews
Human subjects research protocols are also reviewed by the Departments of Pharmacy, Nursing, Biostatistics, Diagnostic Imaging, Biosafety and Radiation Safety, and Cardiology. In addition, a compliance officer reviews all protocols for any issues that may concern a study that involves an Investigational New Drug and/or an Investigational Device.

Methods
Each reviewer is provided instructions for the review process, including specific areas and questions to address. A standardized format is provided to guide the reviewer through the process. These reviews are provided to the principal investigator of the protocol prior to the IRB meeting. The principal investigator then has the opportunity to respond to each of the reviewer’s comments and/or questions and correct any outstanding issues.

Conclusions
All critique-related documentation is provided to the IRB committee members for review prior to and during the scheduled presentation of the protocol on the IRB meeting date. The scientific review process allows for a seamless and intense analysis of the human subjects research conducted at M.D. Anderson Cancer Center, making for a well-documented review.
Assessment of Vulnerability and Risk: IRB Attitudes Toward Medical and Psychiatric Patients
Authors: Luebbert RA; Chibnall JT; Deshields TL; Tait RC

Background
While individuals with psychiatric illnesses are widely recognized as vulnerable to coercion in clinical research, individuals with disabling physical illnesses are considered less vulnerable despite similar threats to autonomy. Unless an illness directly affects brain function, providers tend to presume competence in individuals with physical illnesses. Whether IRB members have similar attitudes, however, is not known. The present study examined the influence of illness type and severity on perceptions of IRB members regarding patient vulnerability and consent competence.

Primary Hypotheses
(1) Patients with psychiatric illnesses will be considered more vulnerable and less competent than patients with medical illnesses; (2) patients with a higher illness severity will be considered more vulnerable and less competent than patients with a lower illness severity.

Methods
Vignettes were developed that represented one of two levels of disease severity (high/low) for four illness types, two representing psychiatric (depression, schizophrenia) and two representing medical (cancer, diabetes) diagnoses in a 2 x 2 x 2(N) experimental design. IRB members were mailed one vignette (determined randomly) that described a clinical trial scenario relevant to one of the eight experimental conditions. After reading the vignette, IRB members rated the hypothetical subject on a range of variables, including measures of vulnerability and competence to provide consent.

Results
Preliminary analyses based on data provided by 113 IRB members (data collection is ongoing) supported the main hypotheses. Patients with psychiatric diagnoses were rated as significantly more vulnerable to coercion (P < 0.001) and less capable of providing autonomous, informed consent (P < 0.001). Patients with diabetes, even those with severe neuropathic pain were viewed as much less vulnerable than other patient groups (P < 0.001). In terms of informed consent, patients with schizophrenia were viewed as the least capable (P < 0.001). Interestingly, all (100%) patients with diabetes were viewed as competent, and patients with cancer, including those with life expectancies less than 6 months, were viewed as more competent than those with psychiatric diagnoses (P < 0.05).

Conclusions
IRB member perceptions of vulnerability and consent competence are consistent with previously documented attitudes of clinical investigators. The perceptions suggest a predisposition to augment vulnerability and discount the capacity of patients with psychiatric diagnoses to provide informed consent. More importantly, the perceptions seem to discount the vulnerability and overstate the competence of patients with medical diagnoses, ignoring the likelihood that psychiatric distress often attends patients with terminal illness and/or with disabling symptoms such as pain.
Bridging the Gap: Improving Communication between the Institutional Review Board and the Research Community
Authors: Wanda A. Quezada, CIP, Martha J. Matza, MS

Background
The Institutional Review Board (IRB) serves as an oversight committee whose primary purpose is to ensure that human subjects participating in scientific research are treated fairly and ethically. Furthermore, the IRB must review research projects to guarantee that the research project is scientifically sound and that subject rights are suitably protected. As a result, communication between the IRB and the research community must be encouraged and preserved to ensure that research projects remain in compliance with federal regulations and that subject rights are continuously protected.

Methods
The M.D. Anderson research compliance staff has devised methods to effectively communicate changes in human subject research regulations to the research community. The staff assembled a “Human Subject Research Manual” (HSRM), which is accessible to the research community by using an intranet web application. The HSRM is a resource database containing both federal and institutional policies governing human subject research. The manual is continuously updated to provide accurate information. Secondly, the staff initiated an electronic monthly newsletter that is provided through the institutional email system. The newsletter informs the research community of new or modified federal regulations and any changes in institutional policies that govern research. Reminders of current issues are included and clarification of any procedures is provided as a form of continuing education for the research community. The need for a system that permits the research community to receive immediate responses to questions was identified and a telephone help line was created as a one-stop phone call. A staff person is on call 24 hours a day, seven days a week. Additionally, many people prefer a face-to-face encounter and for this we provide a central hot topic office for the research community to visit and voice their concerns and ask questions during normal working hours. Staff members provide information and direct the research community to the appropriate sources so that their concerns and questions are answered in a timely manner. The hosting of IRB Open Forums has become an important tool for communicating pressing issues as well. These informal discussions between the IRB committee chairs, IRB members, institutional officials and the research community are held on a bi-monthly basis. An IRB Help email address was also developed to provide status updates on IRB submissions and provide an avenue for the research community to have regulatory concerns addressed.

Conclusions
The implementation of these processes has enabled the IRB to foster communications between the IRB and the research community and thus has allowed the IRB to increase both the investigators’ and institution’s awareness of critical changes in the regulations and policies governing human subjects research protection.
Children’s Oncology Group Central IRB Survey
Authors: N. Ajoy Mathew, JD, MHS; Gregory H. Reaman, MD

Objective
The purpose of this study was to determine the level of interest for a central IRB within key sectors of the pediatric oncology community. The study results, if favorable, would then be used to develop a central IRB for pediatric protocols, which would facilitate implementation of research studies, particularly those that may not have a high priority for local IRB review because potential accrual is low. This study assessed the views of principal investigators (PI) and local IRB Chairs toward the performance of their local IRB with respect to the review of pediatric oncology protocols, the views toward the currently functioning Central IRB administered by the National Cancer Institute for adult oncology protocols, and the interest among Principal Investigators and IRB Chairs in establishing a central IRB that would review pediatric oncology protocols.

Methods
The data were collected via a survey that assessed perception/attitude of the respondents, and was not designed to quantitatively assess PI/IRB Chair characteristics, local IRB performance, etc. within a statistical framework. The study sample consisted of the COG Principal Investigator and an IRB Chair that could be identified at each COG Member Institution. Approximately 476 surveys were disseminated to more than 200 COG Member Institutions, with one survey targeted to the COG Principal Investigator and another to the relevant local IRB Chair. The dataset for analysis consisted of those responses that were received by COG within a specified timeframe.

Results
Respondent Characteristics: Of the 476 surveys disseminated, 236 were returned, a 50% compliance rate. Sixty-one percent (61%) of the respondents were PIs, and 36% were IRB Chairs; eleven percent (11%) were from rural areas, 44% from urban areas, 42% from mid-sized cities.

Respondent Views towards Local IRB Performance: A significant majority of respondents (85%) agreed that patient safety and welfare are adequate at their Institutions. Most IRB Chairs (90%) stated that the Institution’s local IRB had expertise to review pediatric protocols. About 1 in 3 PIs (35%) disagreed or were neutral as to whether their IRB had the relevant expertise to review pediatric protocols.

Views toward NCI Central IRB: Of those familiar with the NCI Central IRB, about half of respondents had a favorable impression of the NCI Central IRB; of the remaining half, the responses did not indicate a clear pattern of neutrality or opposition.

Views toward Establishing A Central IRB For Pediatric Protocols: Seventy five percent (75%) of PIs responding expressed interest in developing a Central IRB for pediatric protocols, 38% of IRB Chairs expressed interest; 15% strongly expressed disapproval of a central IRB. There were no strong preferences on model, whether inside COG, NCCF, or NCI.

Conclusions
Based on analysis of the survey results, it was determined that there was significant support among a key sector of the pediatric oncology community, COG PIs, for establishing a central IRB to review pediatric protocols; additionally, a portion of the IRB chairs did express some measure of support for the concept, although there was some opposition. These results were communicated to the National Cancer Institute (NCI), specifically the Cancer Therapy Evaluation Program (CTEP). COG is currently working with CTEP and other divisions of NCI to establish a central IRB for pediatric protocols. This involves constituting an appropriate panel of experts to review protocols and to develop appropriate policies and standard
operating procedures. This pediatric central IRB is scheduled to begin operation at the end of this year, likely during November 2004.

Authors: Karen Hansen, Helen McGough, Renee Holt, Danna Flood, David Borasky, Tonya Villafana, Joseph Mufutso-Bengo, Shenaaz El-Halabi, Maureen Power

Overview
Protections (PEHRP), was held in Blantyre, Malawi in May 2004. The five-day training was a collaboration with the NIAID Division of AIDS, FHI, FHCRC, University of Washington, Public Responsibility in Medicine and Research (PRIM&R), and the University of Malawi College of Medicine.

The FHCRC and FHI were awarded Human Subjects Research Enhancement grants from the National Institutes of Health in 2003. Such grants are intended to strengthen oversight of human subjects research at institutions like FHCRC and FHI that receive significant NIH support for clinical research, as well as foster partnerships that will help strengthen ethics programs at institutions with less experience in enhancing human subjects protection. FHCRC and FHI focused parts of their grant awards toward ethics review committees in Botswana, Malawi and Zambia. FHCRC initially performed a focused, personalized training with two ethics committees in Gaborone, Botswana. Thereafter, both FHCRC and FHI participated in the PERHP workshop.

Seventy-nine representatives from Botswana, Cameroon, Ethiopia, Ghana, Kenya, Malawi, Nigeria, South Africa, Tanzania, Uganda, USA, Zambia and Zimbabwe, attended training sessions and presented talks on issues relevant to their settings. The United States federal government funds many of the research studies reviewed by the African Ethics Committees. Therefore, the training was also intended to help strengthen their understanding of the history, ethical principles, regulatory compliance and informed consent requirements guiding United States federally funded research. The agenda included review of the US requirements for ethical review of research, information on how to document committee work, small-group discussions on the challenges faced by ethics committees, mock reviews of research protocols, and a poster session in which committees shared successful processes and approaches. Conference presenters--more than half of which were from Africa--offered perspectives on the major ethical principles of autonomy, beneficence, respect, and justice. Discussions initiated at the conference are continuing through a list-serve created by FHI specifically for the attendees. The Collaborative IRB Training Initiative (CITI) has also provided PEHRP Africa conference participants access to the CITI web-based human subject protection education modules.

Lessons Learned
There is an ongoing need to strengthen regional capacity through continued collaboration and dialogue in the regulatory and ethical review processes. The African perspective is critical when applying the ethical principles of autonomy, justice and beneficence in the local context.
Communicating with Students as They Navigate the Human Subjects Approval Process
Authors: David M. La Fazia, MSW; Peggy West

Overview
Navigating the human subjects approval process can be challenging for even the most seasoned researchers. For students, the process can be daunting, often leaving them disillusioned. To support the growing number of students submitting applications for human subjects' approval, we created a program within the School of Social Work to assist students with the process. A doctoral student was hired at .50 FTE to serve as an advisor to students. This person also was appointed as a voting member of an Institutional Review Board (IRB) Behavior and Social Science Committee for the University. Presentations on ethics with human subjects were given in all Master's level research methods courses at the beginning of the two-quarter course sequence and in a PhD level course. Students were invited via a variety of methods (i.e., e-mail, flyers, etc) to meet with the advisor for assistance with human subjects questions and applications. Students were assisted with understanding issues of risk and benefit, recruitment and consent, privacy and confidentiality, completing applications, and responding to concerns of the IRB to name a few of the activities that the advisor facilitated. At the conclusion of the academic year, over 30 students had sought individual assistance from the advisor and nearly 100 students had been reached through classroom presentations. Professors and students were extremely satisfied with the availability and utilization of the advisor. The results suggest an on-going need for programs such as this. The program and its implications are discussed.
A Computer Based Learning Program to Teach Non-Research Clinical Staff About Clinical Research Data Collection
Authors: Cheryl M. Chanaud, PhD, CCRP; Amy Doville, MBA, CCRP

Overview
The purpose of this poster presentation is to introduce a newly developed computer-based learning program for non-research clinical staff who are partially involved in caring for or treating research study participants. Most organizations and institutions do not have formal training programs in clinical research for non-research staff. This learning program, which is available via the Internet, fills a significant gap in clinical research education. The poster is targeted to all clinical research professionals, especially those that are involved in education at their home organization or institution. It is hoped that viewers of the poster will share information with their clinical staff co-workers about accessing this educational program.

Background
Many clinical research studies are conducted with participation of non-research personnel, such as clinical nurses, laboratory technicians, pharmacists, diagnostic imaging technicians and others. These professionals usually have minimal education regarding human subject research, the research consent process, research data collection requirements, adverse event reporting or the federal regulations governing such research. Research nurses at our institution identified this issue as significant and without a mechanism to address it.

Methods
We developed a computer-based learning program composed of four distinct modules. Each module includes specific research information, with each module building upon the information contained in the previous module. To enhance participant interest and comprehension, each module includes audio and video components. In addition, each module includes quiz questions interspersed with the presentation of new information, permitting the participant to self-evaluate their learning. The titles of the modules are:

- Module 1: Clinical research: What it is and how it pertains to the clinical staff member
- Module 2: Patient medical data, patient research data, and the research protocol
- Module 3: The role of the clinical staff member in collecting and recording patient research data in accordance with good research practices
- Module 4: Practical research data collection

Results
We are making this learning program available globally to all healthcare providers at the following website: www.Cure4Kids.org. This educational development program was funded by the Office of Research Integrity, Department of Health & Human Resource and the American Lebanese Syrian Associated Charities.

Conclusions
Computer-based learning modules can be effectively utilized to teach complex clinical research topics to non-research trained healthcare professionals.

Please Note
Presentation of project results is part of the project dissemination plan. A similar abstract has been submitted to the Association of Clinical Research Professionals.
Continuous Quality Improvement Program  
Authors: Helen Panageas, Lauren Petersen

Purpose  
The purpose of the Continuous Quality Improvement (CQI) Program is to establish and maintain a systematic approach to continuous improvement of the quality of research practices. This approach will establish systems to identify deficiencies in the practice of human subject research and implement strategies for improvement.

Goals  
The primary goal of the CQI Program is to improve the quality, performance, and efficiency of clinical research. The CQI Program seeks to foster collegial relationships and create an environment that will enhance networking relationships among researchers. Finally, the CQI Program seeks to promote the development of clinical research within the Institution and the local community by providing educational opportunities to research professionals and community members.

Overview of CQI Program Components  
The CQI Program consists of several components; the Quality Assurance (QA) Review, Investigator/Staff Education, Participant/Community Education, Departmental/Divisional Research QI Activities, Voluntary Human Research Protection Accreditation.

Quality Assurance (QA) Reviews  
Through a three stage process of a Self Assessment, On site Visit and a Consultation on Improvement, the QA review program is designed to identify common causes or defects that may be inherent in the processes used in research involving human subjects. An Off Site Reviews of protocols that are considered less than minimal risk (Expedited or Exempt projects) will also be included in the QA review through a Self-Assessment process. The QA Review component also includes External Audit Preparation and Feedback to assist research teams as they prepare for upcoming audits by the FDA, NIH, Cooperative Groups, or other external agencies.

Investigator and Staff Education  
Educational opportunities will focus on research ethics, human subjects safety, and GCPs. The different programs include: a monthly seminar series for research personnel, monthly research coordinator meetings, training courses in the proper conduct of clinical trials and Good Clinical Practices, and assistance with obtaining certification for Clinical Research Coordinators.

Outreach Initiatives  
Under the aegis of the Institution's Perspectives in Health series, programs will be sponsored at least annually on what it means to be a research subject, how to be a self-advocate as a research volunteer, why Winthrop conducts research and how to potentially participate. Educational pamphlets have been developed in several languages for distribution at these sessions. Presenters will comprise different personnel involved in the administration and conduct of research and members of the community who have participated in clinical trials.

Departmental/Divisional Research QI Activities  
Clinical research is discussed within the framework of Departmental/Divisional QI Committees. These Committees will be required to share trends and issues with the CQI program and other departments.

Voluntary Accreditation Process  
External accreditation of human subjects research activities at Winthrop will function as another key
aspect of the quality improvement activities of this program. A comprehensive accreditation process examines all aspects of the institutional structure supporting clinical research. The institution will seek accreditation through the Accreditation of Human Research Protection (AAHRP).

The CQI Program will be evaluated for effectiveness on an annual basis. Evidence of improvement include; evidence of improved research processes based on comparative department/division specific QA review results from one year to the next, annual review of education programs offered to personnel through different survey tools designed for this program to assure accuracy in current research modalities, and through the successful achievement and maintenance of accreditation; which will in and of itself be an assessment of this component of the CQI process.
Decision Monitoring After Informed Consent: Given Time to Reconsider, What do Subjects Understand; Do they Change their Minds?
Authors: Barbara Frentzen, ARNP, MSN; Susan C. Horky, LCSW

Overview of the Project
For informed consent to be both meaningful and ethical, it is essential that potential research subjects understand information presented to them during the informed consent process. Decision Monitoring is a method to evaluate subjects' understanding of information presented during the informed consent process. A person not directly involved with the study talks with each subject (and each subject's parents when children are involved) after the consent process has been completed to assess whether participation is both voluntary and Decision Monitoring for two early-phase gene transfer trials was initiated on the General Clinical Research Center at the University of Florida. A Decision Monitor asked subjects predetermined questions designed to assess their understanding of the purpose, possible benefits, and potential risks of the study. In addition, the Decision Monitor elicited information about the subjects' reasons for wanting to be in the study, their understanding that participation was voluntary, and whether, having had more time to think about the study, they still wanted to participate. Results were also tabulated from a "natural experiment" that occurred when all subjects had to be re-consented because they did not sign a HIPAA authorization form when initially enrolled in a study involving donation of a blood sample to a DNA Bank.

The experiences of two Decision Monitors were retrospectively reviewed and data from the "natural experiment" were tabulated. The goal was to evaluate the experience and to generate hypotheses for future research.

Conclusions
1. After reading an informed consent form, listening to a verbal explanation, and agreeing to participate in a study, some subjects still misinterpret the purpose, risks, or benefits of that study.
2. In this review, misunderstanding of clinical care vs. research was signaled by a subject's assertion that the physician was trustworthy and would "do nothing to hurt me".
3. Some subjects may not fully understand the risks and benefits while others may understand but retain an optimistic outlook. Differentiating between the two situations can be challenging.
4. Given a specific opportunity to withdraw, some subjects will choose that option.
5. Prospective research about the value of decision monitoring is needed. Does Decision Monitoring improve informed consent? Do subjects find it easier to tell a neutral person like the Decision Monitor that they do not wish to participate? Do subjects who participated in Decision Monitoring appreciate it or feel that it is burdensome? Do researchers find this additional layer of the consent process helpful or interference?
Does a Signed Informed Consent Form Assure Informed Consent?
Authors: Frances S. Crosby EdD, Darlene Campanella, Monica Spaulding, MD

Background
Respect for persons, one of the three key principles of the ethical conduct of research using human subjects (Belmont Report, Fed. Register, 1979), requires that people have a right to voluntarily choose to participate in research or not. Informed consent has evolved to a formal process with legal implications as a research tool to establish voluntary research participation. Informed consent includes information, comprehension and voluntariness (Dunn & Chadwick, 2002). While presentation of information about the study of interest can be assessed by the IRB and voluntariness can be assumed by a witnessed subject's signature on a consent form, comprehension is a more elusive, yet equally important, quality.

Purpose
A quality improvement project was conducted to determine if the comprehension element of the informed consent process could be assessed. The question was: Do research subjects who signed an informed consent to participate in a research study perceive after the study that they had comprehended the information they received about their participation which enabled their voluntary agreement to be in the study?

Methods
A retrospective mailed survey was sent to 30 research subjects who signed an informed consent form and had completed one of three research studies at a clinical research center for multiple sclerosis. For the sample, Study 1 included all subjects enrolled (n=20), Studies 2 & 3 randomly selected 5 out of 13 and 18 subjects enrolled respectively. A cover letter described the purpose of the survey and assured anonymity of response via an enclosed envelope addressed to the IRB. The survey presented 12 items with closed (yes/no) response options, and space for added comments. Items elicited information about adequacy of information given, comprehension after actually participating, and voluntariness of agreement to be in the study.

Results
An overall 90% response rate was achieved. Respondents unanimously indicated they had enough time and information to make an informed choice, had their questions answered satisfactorily, felt they were given the choice of whether to participate or not and understood what the research was about. Almost all respondents were given a copy of their consent, did not feel forced to participate, knew they could decline and still receive usual care, understood what was being asked of them, and knew what to do and whom to call in case of a problem. The majority indicated that words were explained to their satisfaction, while the remainder noted their were no words that they needed explained. Most indicated they knew of the risks (21) and the remainder indicated there were no risks (6). Comments were positive about participation in the study. Some negative comments indicated desire for follow-up information about the results, and not receiving reimbursement for parking.

Conclusions
This is a pilot study of 30 subjects, so definite conclusions are not made. Results of the pilot suggest that a mailed survey is an effective tool (90% response) to ascertain the comprehension and voluntariness of informed consent. Results also suggest that subjects felt adequately informed and freely consented to be in the MS treatment related studies. Further research is warranted on a larger sample to make more than preliminary conclusions. The risk item needs further attention, as "risk" had been addressed in the consent document yet 25% indicated "no risks."
Educating Promotores on Ethical Practices and Principles to Enhance Human Subjects Protections

Authors: Camille Nebeker, MS; Karen Coleman, PhD; John Elder, PhD, MPH; Michael Kalichman, PhD; Lori McNicholas, PhD, RD; Gayle Simon, MPH; Gregory Talavera, MD, MPH; Ana Talavera, MPH; Jennifer Terpstra, BA

Background

Investigators conducting research in Latino communities increasingly rely on the Community Health Worker/Promotore model to deliver public health interventions. The role of the Promotores is to maintain a positive rapport with community members while delivering health interventions to Latino communities. Promotores responsibilities range in complexity and include intervention delivery, participant recruitment, screening, selection and consent, data collection and management, and serving as a liaison between the researcher and the community under study. Due to the critical role and responsibilities that Promotores hold in research targeting the Latino community, the need for culturally tailored training materials that focus on ethical research practices has been recognized.

Project TRES (Training in Research Ethics and Standards) is funded by National Institutes of Health to develop, disseminate and evaluate a culturally tailored, content-appropriate, Spanish-translated research ethics curriculum that targets Community Health Advisors/promotores delivering research to the Hispanic/Latino communities. The curriculum developed will rely on The Belmont Report to guide the ethical concepts of each module. We will describe the curriculum development process and provide samples of training materials developed. Design recommendations from key stakeholders (investigators/managers (n=9), and promotores (n=19)) obtained during focus groups and interviews mirrored our expectations for standard course concepts and identified cultural barriers to training. Not anticipated was the need to include instruction in basic research design and methodology. Format recommendations focused on simplicity of presentation and use of culturally relevant scenarios/case studies (video, role-plays) that allow for demonstration of the ethical principle/concept using examples/case studies depicting real examples from the field.

Learning Objectives

1. Describe a model used to develop culturally tailored educational materials;
2. Articulate training content and format priorities identified by both research investigators/program managers and promotores;
3. Identify potential cultural barriers to training research ethics within the Latino community.
Electronic Submission of Unanticipated Problems
Authors: Patricia M. Scannell, BA, CIP; Philip A. Ludbrook, MD; Denean Marie; Courtney Beers BA, CIP; Deb Thompson; Timothy Walton, BS, CIP; Sarah Frankel, PhD; Melissa Torres, MSW; and Diane Clemens, DC

Background
In one year Washington University School of Medicine's IRB reviewed 10,730 serious adverse event reports. This volume made the development of an electronic submission process essential to increase the efficiency and effectiveness for all parties involved in human subject research protections. To aid other investigators, study coordinators, IRB members and industry sponsors, this poster will: identify how an electronic screening tool can assist with the submission of unanticipated problems, list areas that need to be considered when developing an electronic submission tool, and describe the process used when developing an electronic submission tool.

Overview of the Project
There are many steps and considerations that go into developing an electronic system for unanticipated problem submission. Amongst those are:

- **Process Issues**
  - **Environmental Assessment:** Make a compelling case for the changes you are anticipating with every substantive stakeholder.
  - **Visioning:** Bring together some of the stakeholders - faculty and staff - and conduct a highly focused session surrounding an "idealized state."
  - **Prioritization:** Armed with a good sense of the stakeholders and feedback from the visioning session, priorities should be set.
  - **Readiness Assessment:** Conduct a readiness assessment to describe the state of readiness along with several major attributes and what you will do to address areas of concern.
  - **Technical Assessment:** Only after you have clearly identified the real issues of concern should you begin to address the technical issues. Your technical vision should be driven by the important issues that bring real and immediate benefit.
  - **Communications Strategy:** Develop a means of telling your constituents what it is you are doing and why. You should help set expectations and constantly invite feedback.

- **How the System Works**
  - **Screening of unanticipated problems:** This instrument helps the PI determine what needs to be reported.
  - **Routing of unanticipated problems:** Once reported, the system archives the event or routes it to a reviewer.
  - **Resolution:** Contingencies are communicated to the PI and may be resolved electronically increasing efficiency.
  - **Record keeping:** The system maintains a cumulative report.

Conclusions/Applications
Using the process above, an electronic submission system of unanticipated problems was developed that has improved the accuracy of reporting and reduced the burden of ambiguity for the reviewers.
Evaluating the Readability of Pediatric Research Consent Forms
Authors: SB Blackman, MPH; VE Bovbjerg, PHD, MPH; DT Chen, MD, MPH; PA Lombardo, PhD, JD; ARiffenburgh, MA; RD Stevenson, MD

Background
The impetus for this study was an interest to develop an institutional "pre-IRB review" model. To be efficient, this model should identify variables associated with IRB adjudication. This study explored relationships between the identification of trainees as investigators, external source of funding, and initial adjudication.

Methods
Descriptive analysis. All 47 principal investigators enrolling minors at UVa in August 2003 gave permission to include 116 of 117 (99%) parental consent forms, and all 78 assent forms written for minors 7-14 years of age. Three consent forms were excluded because they did not include the institutional review board (IRB) template. To comply with established methods for using readability formulas, all incomplete sentences were removed from all forms. Readability Calculations software (Micro Power & Light, Co., Dallas) generated grade scores using the Fog and Smog formulas, and reading scores ranging from 0 (most difficult) to 100 (easiest) using the Flesch Reading Ease (FRE) formula. These well-established formulas have been used for decades to evaluate reading levels of school textbooks. Mean scores were reported for assent and consent forms, and for specific consent form sections, including introduction, procedures, privacy, patient's rights, genetic testing and tissue banking.

Results
Readability results for child assent forms were as follows: Fog 8.9, SD ± 1.3; Smog 8.6, SD ± 1.1; FRE 74.0, SD ± 6.3. Readability results for parental consent forms were as follows: Fog 14.1 SD ± 0.8; Smog 12.9 SD ± 0.6; FRE 47.6, SD ± 4.1. Each of the six consent form sections were written at the college reading level. Results were unchanged when stratified by protocol sponsorship or IRB protocol review type. Increasing page length was correlated with more difficult readability in assent forms (r=0.4, p=0.0002) but not consent forms (r=0.0, p=0.93).

Conclusions
Child assent forms, intended for readers 7-14 years of age, were written at the 8th grade reading level. Parental consent forms, intended for the average adult, were written at the college reading level. This might compromise the ability of average parents and children to understand critical information. Until the educational, regulatory and legal purposes of consent forms are disentangled, it seems the tension between readability and comprehensiveness will persist.
Overview

Ethical considerations are important in any biomedical research, but especially so in research involving human subjects. Roche has established a framework for discussing and resolving potential ethical issues that may arise during the course of clinical research. This encourages ethical issues to be addressed in a proactive manner, which facilitates consensus decisions and promotes a shared understanding of the company's corporate values and ethical standards. The preferred model consists of a three step process, through which even the most difficult ethical issues can be resolved.

A Roche employee who feels he is facing an ethical dilemma or who has an ethics question can get in touch with the Global Ethics Liaison. This individual serves as a central contact for uniform advice on ethical issues in clinical research, and is independent from the clinical development teams. Thus, the Global Ethics Liaison is able to help the clinical development teams to find an appropriate answer through open discussion and fact finding. If this is not sufficient, the Global Ethics Liaison will escalate the issue to the Head of Pharma Development and his advisors. If need be, advice can also be sought from an independent external advisory group consisting of bioethicists and other experts from academia and the patient community. Membership of this advisory group is global in character, with current members coming from Asia, Europe, and North America. The main role of this external ethics advisory group is to participate in periodic ethics discussions, serving as a sounding board, and to ensure that Roche is made aware of current external ethical issues in an ongoing manner.

To promote awareness of the process, and to reinforce the company's corporate values and ethical standards, ethics education is offered to employees. During training sessions the benefit of open dialogue regarding potential ethical issues is stressed, and the concept of ethics and what it means to Roche employees in their daily work is explored.

Abstract/Publication Plan

2. External Ethics Committee Concept - CREAG
3. Ethics Education Concept; (a) Awareness, (b) Culture Change, Problem Solving
4. Update(s) on 1-3 as appropriate through time
How Often do Clinical Studies Meet their Enrollment Goals?

Background and Purpose
Many Institutional Review Boards (IRBs) are experiencing an increase in the number of protocols reviewed. At the same time, the amount of time required to review each study has increased. Studies that do not fulfill their projected enrollment still require the same amount of time and effort for IRB review. We examined studies reviewed by an IRB at a large academic medical center for factors that might be associated with low enrollment with the ultimate goal to improve IRB workflow.

Methods
We examined studies approved by the Biomedical IRB at UNC that were closed from 6/2003 through 6/2004 (N=490). We included studies involving therapeutic interventions; those with healthy volunteers; and epidemiology studies. We excluded studies that involved retrospective reviews of patient data or tissue samples and studies done predominantly outside of the U.S. We recorded sponsor's name, type of funding source (e.g., industry or government), principal investigator, investigator's department, level of IRB review, the date when the IRB received the research application, the IRB approval date, the closure date, duration of the study (in months), initial projected enrollment goal, the number of subjects actually enrolled, the number of amendments and renewals, and key words in the study title. If the number of subjects at the time of study closure was not recorded, we used the number from the last renewal. If enrollment goals changed during the duration of the study, the initial enrollment goal was used to calculate the percent of targeted enrollment. Descriptive statistics are displayed for the overall sample and further stratified by several variables.

Results
Table 1: Overall Means for Key Variables Examined, N=490

<table>
<thead>
<tr>
<th></th>
<th>% Goal Accrued</th>
<th>Duration, in Mos.</th>
<th>Orig. Goal</th>
<th>Actual No. Enrollees</th>
<th>No. Amendments</th>
<th>No. Renewals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg.</td>
<td>51.01</td>
<td>33.52</td>
<td>72.60</td>
<td>29.03</td>
<td>2.13</td>
<td>1.81</td>
</tr>
<tr>
<td>SE</td>
<td>8.14</td>
<td>6.16</td>
<td>13</td>
<td>8.8</td>
<td>1.6</td>
<td>1.78</td>
</tr>
</tbody>
</table>

Table 2: Results Grouped by % of Goal, Averages for each group

<table>
<thead>
<tr>
<th>% Goal Accrued</th>
<th>N, Total=490</th>
<th>Duration in Mos.</th>
<th>Orig. Goal</th>
<th>Actual No. Enrollees</th>
<th>No. Amendments</th>
<th>No. Renewals</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>189 (39%)</td>
<td>18.84</td>
<td>63.53</td>
<td>0</td>
<td>1.08</td>
<td>0.56</td>
</tr>
<tr>
<td>1-24</td>
<td>46 (9%)</td>
<td>35.87</td>
<td>116.43</td>
<td>16.43</td>
<td>2.35</td>
<td>2.17</td>
</tr>
<tr>
<td>25-49</td>
<td>46 (9%)</td>
<td>45.46</td>
<td>142.78</td>
<td>50.35</td>
<td>3.13</td>
<td>2.76</td>
</tr>
<tr>
<td>50-74</td>
<td>56 (11%)</td>
<td>45.00</td>
<td>51.96</td>
<td>32.11</td>
<td>3.00</td>
<td>2.89</td>
</tr>
<tr>
<td>75-99</td>
<td>44 (9%)</td>
<td>31.20</td>
<td>76.91</td>
<td>68.36</td>
<td>2.16</td>
<td>1.66</td>
</tr>
<tr>
<td>100</td>
<td>47 (10%)</td>
<td>37.64</td>
<td>78.57</td>
<td>73.57^</td>
<td>1.77</td>
<td>2.30</td>
</tr>
<tr>
<td>&gt;100</td>
<td>62 (13%)</td>
<td>55.81</td>
<td>26.72</td>
<td>61.28</td>
<td>3.93</td>
<td>3.49</td>
</tr>
</tbody>
</table>

^Unequal to prev. column due to rounding; ^Percent of total

Conclusions
Over 1/3 of the studies accrued no subjects. These studies ended earlier on average; they had accrual goals similar to the other subgroups in "% Goal Accrued." The studies that accrued between 1-100% of...
goal varied in duration and goals. Studies achieving >100% of goal had modest initial goals on average. Further analysis of the data will be presented.
Improving IRB Review and Response Time
Authors: Katreena Collette Merrill RN; Paul Urie MD PhD; Doris Fowers

Objective
The IRB initiated a quality improvement project with the following goals:
1. Decrease the time from new submission of a protocol to the IRB review;
2. Decrease the time from initial IRB review to first correspondence to the investigator; and
3. Increase investigator and study coordinator satisfaction with the IRB process.

Methods
The IRB policies and procedures were reviewed and revised. IRB meetings were increased from 6 per year to 10 per year. A computer program (ProIRB®) was used to track new protocol submissions and correspondence. A new application packet was developed with detailed instructions to the PI on how to complete the application. A checklist and consent template was included for writing a consent that included appropriate privacy and regulatory components. New protocol applications were reviewed for completeness by the IRB office prior to submitting them to the IRB for formal review. The following was measured and compared: 1) the time from initial protocol submission to formal IRB review, and 2) the time from formal IRB review to initial correspondence with the investigator. In addition, feedback was solicited from the investigators and study coordinators regarding the changes in IRB procedures.

Results
The average number of days from new protocol submission to the formal IRB review decreased from 24 days to 17 days (p value 0.17). The average number of days from the IRB meeting to initial correspondence to the investigator decreased from 22 days to 5 days (p value .001). Principal investigators and study coordinators reported increased satisfaction with the new IRB procedures.

Conclusions
The requirements for human subjects research and the process for submitting protocols to the IRB can be confusing for an investigator who is not familiar with them. The IRB office can streamline its process to make the research process easier to navigate and more user friendly. Streamlining the IRB process will foster research and promote human subjects safety.
Authors: Marco Better, John Sherman, Megan Colby, Melanie Hargarten, Joseph Rosse

Overview
The success of an IRB is ultimately determined by the ethical and safe treatment of research participants. Reaching this goal requires the cooperation of many parties, including PIs. A slow and cumbersome review process can have a detrimental effect on the cooperation of PIs. Instead of being seen as a benefit to their work, investigators may feel that the review process is an obstacle, a burden, and at worst an evil that can be by-passed. Needless to say, this attitude may bring about serious consequences to the investigators as well as the research institution they represent.

In conjunction with other efforts to enhance the quality of the review process, we have analyzed the human research review process at the University of Colorado at Boulder from a business process design (BPD) perspective. Our study focused on improving those performance measures that are highly valued by the IRB's "customer": the PI. Our empirical data showed that, aside from the quality and consistency of the review itself, turnaround time (the time between submittal and final approval of a research protocol) was the outcome PIs valued most. From an internal process perspective, we also looked at resource utilization rates as well as protocol throughput rates as additional process performance indicators.

The project involved two primary phases. The first phase involved gathering information through interviews, observation and analysis of records to determine the current workflow and relevant baselines statistics. In the second phase we used a discrete event simulation application - Extend by Imagine that, Inc. - to model the current process and to experiment with various proposed scenarios. Working with the IRB staff and the simulation data, we were able to develop a number of recommendations involving such things as:

- Identifying an optimal frequency for panel meetings.
- Assignment of a "case owner" to each protocol, as the single point of contact for that protocol's throughout the process.
- Reducing "hand-offs" of protocols among IRB staff, thus streamlining the flow and reducing the likelihood of misplaced protocols.
- Eliminating, consolidating and reengineering activities.
- Balancing the work load among IRB office staff.
- Improving the speed and rate of the flow of work through the process.

Based on data from the simulation scenarios, the recommended changes are expected to result in a considerable reduction of average protocol turnaround time, as well as reduced variability in turnaround times. We also expect a significant increase in protocol throughput. We are confident that these changes will not adversely affect the quality and consistency of the reviews. We hope that these changes will increase the level of PI satisfaction with the process, resulting in higher PI involvement that will translate into an improvement of the overall quality of the review process, and better levels of compliance of regulations.
Investigator’s Perceptions of Communication from the IRB: How adequately do we convey respect and beneficence?
Authors: Rebecca Ann Lind, Don E. Workman

Background
The subject protections profession is at a developmental crossroad. We have responded to the call for more rigorous processes and documentation to ensure greater compliance with regulatory requirements for protecting research subjects. We have developed training and certification programs, and are creating human protection programs where none existed. Numerous articles have documented our progress, which raises “the bar” ever higher as we try to improve our programs and avoid disastrous outcomes. In addition to this emphasis on protection, some have begun to reflect on how well our human protections administrations incorporate the values of respect, beneficence, and justice in our communications with investigators. A review of the electronic database at the National Library of Medicine (PubMed), using combinations of search terms: ‘IRB,’ ‘customer,’ ‘faculty,’ ‘investigator’ and ‘satisfaction’ provides only one citation (1996). The time has come for us to apply empirical methods to evaluate our communications with investigators. Only then can we begin to implement evidence-based quality improvement programs.

Hypothesis
We hypothesize that investigators will provide feedback regarding their perceptions of their communications with the IRB. Lacking any systematic study, anecdotal evidence leads us to hypothesize that our documents, letters, and online guidance to investigators are not fully effective at communicating the Belmont values of respect, beneficence, and justice.

Methods
For this abstract, we conducted a pilot test of a larger-scale survey (to be conducted in August). We propose to present the results of the larger survey at PRIMR in October. The pilot test used a convenience sample of 20 PIs at a large Midwestern research university; the sample for the larger-scale survey will be significantly larger, and will use more rigorous sampling methodology. The survey contains a mix of open- and closed questions addressing investigators’ evaluation of their communications with IRB; these questions reflect the basic Belmont principles, particularly respect. See attached survey instrument (and approval of claim of exemption).

Results
Investigators are willing to evaluate their communications with the IRB; the mix of open- and closed ended questions effectively elicited feedback. Closed question responses indicate that many face-to-face, telephone, and email interactions with the IRB are positive, but more formal written communications (letters, website) are less so. Open-ended responses show a variety of evaluations from the highly positive to the highly negative; in the larger-scale survey these responses will undergo thematic analysis to identify key strengths and weaknesses in our communications. More detailed pilot-test results available on request.

Conclusions
The conclusions of August’s larger-scale study will allow more definitive conclusions to be drawn; our pilot test shows that some interactions between the IRB and the PIs could more clearly demonstrate the Belmont principles of justice, beneficence, and respect. Our pilot test demonstrated the efficacy of our method. By October we will have a baseline identifying how well we communicate respect and beneficence to investigators, and will be able to provide suggestions for improving the communications between the IRB and investigators. We will make our survey available to PRIMR and conference attendees and are eager to build connections with research administrators with similar goals of improving their communications with investigators.
IRB Guidance on Pediatric Research: What is Helpful or Problematic
Authors: Leslie E. Wolf, JD, MPH; Jolanta Zandecki, BA; Bernard Lo, MD

Background
Pediatric research is essential to promoting the health and well-being of children, but it can also be controversial. In the United States, research with children must follow special regulations that are more restrictive than those governing research with adults. In 2004, an Institute of Medicine (IOM) committee made recommendations about ethical issues concerning clinical research involving children. In particular, the IOM recommended that IRBs develop more specific guidance about pediatric research and disseminate it through their websites. We examined whether and how IRBs are using their websites to provide such guidance to investigators conducting pediatric research.

Methods
We studied guidance on pediatric research from IRB websites at the 25 U.S. medical schools (and affiliates, including hospitals, independent research centers, and public health schools, with separate IRBs) and the 10 children's hospitals that receive the most NIH research funding. We also included one medical school IRB that developed a web-based research ethics training program which other IRBs use.

Results
IRB websites generally provide basic information about pediatric research, including the special federal regulations governing pediatric research and the categories of permitted research. However, there are missed opportunities to help investigators understand the regulatory and ethical requirements for pediatric research. Moreover, some IRB advice may be problematic. More detailed IRB guidance may help protect children in clinical research. Examples of ways to achieve this include checklists and "points to consider," concrete examples to illustrate regulatory requirements, and highlighting areas of controversy.

Conclusions
Few IRBs present the kind of detailed guidance that investigators need to apply ethical principles to specific protocols. IRBs should take advantage of the opportunity to help investigators browsing the IRB website to think through ethical issues that arise in their research. In addition, IRBs should work cooperatively with pediatric professional societies to address controversial issues in pediatric research and develop more consistent guidelines.
Institutional Review Board Turn Around Time
Authors: Kelly L. Culbert, MS Ed; Douglas S. Diekema, MD, MPH; Elizabeth Trias, MA, CIP

Background
Research investigators commonly express concern that obtaining IRB approval is a time consuming process. In the interest of improving IRB turn around times (TAT), we developed a database that allowed tracking of times from submission of an IRB application to approval. This database also allowed us to determine how much of the TAT was the responsibility of the IRB.

Hypothesis
We hypothesized that most research applications experiencing delay in approval were related to delays of investigators responding to requests for information and contingency as opposed to delays in IRB processing.

Methods
Metrics for all research applications were recorded from time of preliminary review submission through date of approval for the time period January 1, 2004 through June 30, 2004. Processing times were attributed to either IRB TAT, Principal Investigator (PI) TAT, Scheduling or Negotiation.

Results
The median length of time from IRB application submission for pre-review until final IRB approval was 58 days (range 29 to 385 days). When broken into individual components, median times included 16 days in pre-review, 8 days awaiting a scheduled meeting, 5 days between the IRB meeting and a letter addressing contingencies being sent to the PI, 2 days of negotiation regarding contingencies, and 18 days awaiting a response to contingencies by the PI. On average, a median of 10 days passed during which an application was being processed by the IRB. A median of 30 days was spent awaiting submission of a final application and response to contingencies by the PI.

Conclusions
The data reflected a wide range in TAT for IRB applications. The data also suggests that at least half of the time required for IRB approval is time taken by the PI to respond to requests and contingencies.
IRBNet: The Networked IRB
Authors: Elizabeth Bankert, Robert "Skip" Nelson

Objective
The objective of IRBNet was to create a virtual site to facilitate the conduct of multi-site research, including protocol development and cooperative IRB review. CHOP and Dartmouth pooled their resources from the NIH IRB Enhancement Funding program to create the IRBNet site, located at http://www.irbnet.org.

Methods
The website was created based upon review of ethical principles guiding research with human subjects, federal regulations, International Committee for Harmonization guidance and discussions with many IRBs, Researchers, and Sponsors.

Results
IRBNet is a centralized and secure web-based database, with the specific aim of making possible an effective and efficient means of education and communication among IRBs, researchers, and sponsors particularly with multi-site studies.

Summary of Features
1. The system is accessible via the World Wide Web.
2. The system has 3 modules: Education/Development, Distribution/Archive, and Database.
3. A “help” function is accessible in each module to provide information about different components and functions of each module.

Module 1: Education - Protocol and Consent Form Development
1. The education module provides up-to-date information on protocol and consent development as well as links to other educational sites, i.e. FDA, OHRP, etc.
2. The education module allows interactive text-entry to create protocol/consent forms.
3. The user may save entries as s/he completes each field.
4. The user may save an incomplete study plan and return to it at a later date.
5. The user may use an “upload” function to include site-specific information.

Module 2: Sharing and Distribution
1. The distribution module will house protocol and consent forms developed in Module 1, as well as pharmaceutical companies’ protocol and consent forms.
2. It allows sharing of protocol and consent forms between researchers at multiple sites.
3. The user will be able to revise housed protocol and consent forms before and after IRB review.
4. User will be able to print forms.

Module 3: IRB Review Status Database
1. The IRB review status with participating IRBs can be determined via a search of the multi-site title.
2. IRB contact information is available for further discussion.
3. Allows communication which may lead to acceptance of another IRB as the IRB of Record.

Conclusions
IRBNet is a source of education to researchers in the development of protocols and consent forms as well as a system to assist in the coordination of activities of multiple IRBs when participating in multi-center research studies. IRBNet will be available to all institutions across the country and thus this initiative is indeed a shared resource. IRBNet promotes education, standardization and communication.
Launching the IRB into Cyberspace: e-Enabling Board Review Near and Far
Author: Kersten Hubbard, MD

Overview
As institutional review boards continue to grow and more regulations regarding research in human subjects are written, the amount and format of material to be reviewed at a single board meeting has become cumbersome. Western Institutional Review Board (WIRB) chose to address this issue by promoting, developing, and implementing an electronic board packet (e-packet). This presentation will describe in detail the approach to this systemic transition and offer suggestions about how other IRBs may approach this endeavor.

The e-packet has proven to be easy to build, read, use during meetings, and transport; economical to produce, ship and use; palatable for all users; culturally compatible; and expandable for future uses. Many of the necessary items for conversion from paper-based review materials into electronic media already existed within the organization's infrastructure.

Board member and staff training were completed within a two-month time frame. Most e-packet users converted from paper packets to electronic packets by their second meeting. By the end of the second month, all 70 board members and approximately 40 WIRB employees were using e-packet exclusively. Beyond the cost savings in raw materials, printing, labor, shipping, and document security issues, e-packet has provided for other operational processes to be developed which further enhanced customer and board support.

Capital investment for the project was approximately $1200 per board member. It is estimated that the project will have paid for itself by the second quarter of implementation. This savings does not reflect the increased revenue which is indirectly a result of e-packet, such as improved operational performance, enabling board meetings which include participants from remote sites, and facilitating communication with consultants. The growth of a business is not just seen in the number of employees, but also in how an organization handles information. Choosing to update information strategies is critical in the current business climate. Fortunately, the computer era has generated many options for today's businesses.
Medical Schools' Attitudes and Perceptions Regarding the Use of Central Institutional Review Boards (IRBs)

Authors: Evangeline D. Loh, PhD; Roger E. Meyer, MD

Background
The use of central Institutional Review Boards (IRBs) at medical schools and teaching hospitals for review of clinical research and human subject protection (HSP) is a recent phenomenon. While federal agencies, and a recent communication from the Association of American Medical Colleges (AAMC), have highlighted the acceptability of reviews of clinical research by non-institutionally-based IRBs, it is not known how common the practice is within academic medicine, what the attitudes of institutional leaders are toward the use of central IRBs, and what the experience has been among institutions that have used central IRBs as part of their HSP activities. With the recent introduction of accreditation of human research protection programs, it is likely that institutions will be better able in the future to evaluate the quality of their programs, and the benefits and costs associated with different types of review. At this time, there are no systematic data that bear on this question. This poster will report on a survey of current practices related to the use of central IRBs at U.S. medical schools: the current practices, attitudes, perceptions, and future plans of US medical schools regarding the use of a central IRB to review research involving human participants.

Methods
A survey instrument was distributed to the official in every American medical school who decides on the use of a central versus local IRB. Responses were analyzed for 88 institutional representatives, who completed the survey.

Results
of the medical schools responded, 76% of these institutions indicated that they had never used a central IRB and 24% of these institutions had. Most of the institutional respondents expressed no interest in using a central IRB in the future because they believe that their institutional IRB is working efficiently, and they are concerned about issues of institutional liability and the loss of local representation in the review process. Of the institutions that had used a central IRB, most were pleased with the performance of the central IRB and would continue to utilize a central IRB in the future. Of interest, most of these respondents did not agree that a central IRB had helped them to attract industry-sponsored research.

Conclusions
In spite of much discussion about the advantages of central IRBs in expediting overview of human subjects research, especially in multi-center trials, the majority of medical schools surveyed have never used a central IRB and express no interest in doing so.

Necessary Elements in Fundamentals of Human Studies Research
Authors: Sarah Frankel, PhD; Melissa Torres, MSW; Brian Springer; Kathryn Britton; Anna Eccher; Phyllis Klein, RN; Michelle Jenkerson, RN; Mickey Clarke, and Katarzyna Karelus

Background
In 2001, the National Institutes of Health (NIH) strongly encouraged anyone conducting human studies to be trained. The NIH composed a committee of scientists, clinicians, lawyers, ethicists, research administrators and consumer/patient representatives. They found “four specific conditions that should be pervasive within the research culture.” (IOM, 2002) One of those conditions was “ethics education programs for those that conduct and oversee research.” (IOM, 2002) Ethical commitments must be seen as the core of research and in order for this to occur ethics must be given a central role. (Kahn and Mastroianni, 2002) It was also noted that more research needs to be done on the outcomes of training as it relates to conduct of research and that this research should be conducted by education specialists. (Midwest Bioethics Center, National Conversation, 2004) In order to accomplish this, the Necessary Elements in Fundamentals of Human Studies Research was developed as a collaborative effort between the Human Studies Committee (HSC), Center for Clinical Studies, General Research Center, and the Siteman Cancer Center at Washington University School of Medicine.

Purpose
This is a 17.5 hour course delivered over a five-week period. The course is offered twice each year. This course is intended to provide the participants with information from as many areas of research as possible so that they are exposed to various types of research conducted at Washington University. The immediate objective is to educate investigators and research staff in the ethics of research. The long-term goal is to have all investigators properly trained.

Overview of the Project

- **Evolution and History of Human Subject Research**
  Objectives: Explore the history of research ethics and emerging ethical considerations as new fields emerge. Learn what lead to the formation of current regulations governing human subject research, their implications, and how research is governed.

- **The Research Process**
  Objective: Provide an overview of the research process from study origination through data collection an analysis.

- **Overview of Good Clinical Practice**
  Objective: Understand and be able to apply the elements and principles of Good Clinical Practice

- **Institutional and Investigator Responsibilities**
  Objectives: Explain responsibilities from study initiation through closure.

- **Current Issues and Future Considerations**
  Objective: Discuss current topics.

Conclusions
Attention to the ethics and the conduct of research is essential for any person involved in research with human subjects. The necessary elements in designing a course of this nature, provided in this poster, will benefit any person involved in the protection of human research participants.
Not For Cause Review Program
Authors: Jonathan Davis, MD; Helen Panageas; Tina Berry

Purpose
The Administrative Office of the Institutional Review Board Committee (IRB) has implemented a program for conducting routine "not for cause" reviews of studies approved by the Winthrop IRB. The purpose of the review program is to assure that the rights and well-being of human subjects are protected and that the study is being conducted in compliance with the currently approved protocol, federal regulations and WUH IRB policy.

Objectives
The primary objective of the review program is to identify areas of non-compliance. The secondary objective is pro-actively resolve and prevent situations that might place additional risks on human subjects and/or lead to regulatory citations if the research were to be reviewed by an outside entity.

Overview
The program is managed through the Administrative Office of the Institutional Review Board Committee (IRB). The IRB Director, IRB Manager and an IRB Member with scientific expertise, the Review Team, conduct reviews on a monthly basis. Trials that include greater than minimal risk, vulnerable populations or other sensitive issues are given priority in the review program.

Methods
The scope of the review is based on considerations such as the trial objectives, design, complexity, blinding, and size. A research investigator is selected for a review. The number of trials reviewed depends on the number of trials under the direction of the investigator. Approximately 10% of the investigator's total trials or caseload are chosen for the review.

The investigator receives an electronic mail notification from the Director of the IRB that indicates the intention and establishes the time and place for the review. The Investigator is encouraged to meet with the Review Team at the start of the review to answer any questions and again to be present at the end of the review. However, an Investigator's presence is not required. The Review Team must be given access to the records and be provided with a suitable private workspace.

A data collection sheet is employed to establish the accuracy of the research data collected by the Investigator and determine compliance to the protocol and congruency to IRB records. Parameters examined include, but are not limited to:

1. Regulatory files - for required elements including: presence of required documentation of protocol approvals, amendments to the protocol, approved consent forms, all IRB documentation, adverse event reporting, confidentiality of records, and drug or device handling and accountability.
2. Subject files - a random sampling of subject files are selected from the total number of subjects enrolled to the trial. The files are reviewed to determine subject eligibility, subject history, Informed Consent documentation, Concomitant medications/ therapy, laboratory data, and accuracy and completeness of Case Report Forms.

Once the review has been completed, the Review Team will conduct an exit interview with the PI and appropriate study staff. The review team does not discuss deficiencies found during the course of the review with the investigator, but will discuss preliminary findings. This interview provides opportunity for immediate dialogue, responses and/or clarification.
All findings are documented by the IRB Director in a draft not for cause report for review and comment by the IRB Chairperson within 48 hours of the conclusion of the review. A final report detailing findings and recommended corrective action is sent to the PI within five to ten working days from the conclusion of the review. The PI is asked to respond in writing and provide a final corrective action plan. If necessary, the IRB Chair and IRB Director assist investigators and study staff by providing consultations in the development of satisfactory corrective actions. All findings, recommended corrective action and the Investigator's comments are presented to the IRB Committee for review, discussion and comment. The Investigator implements the plan once a satisfactory corrective action plan is determined and agreed upon by the Investigator and the IRB.

Results
Twenty-five Not for Cause Reviews (forty-five trials) have been conducted from 2002-present. Common findings include; unreported protocol deviations, adverse events and modifications to previously approved protocols, missing lab results in subject files, FDA 1572 forms missing, use of incorrect Informed Consent documentation, improper witness signatures, expiration of project approval and lack of documentation of investigators presence during consent process. In 2005, the Review Team will be revisiting Investigator's reviewed since 2001. The review program will expand to include a comparison of previous findings to new findings that will be shared with Investigators.
OCREB: A central research ethics board for cancer
Author: Sidney R. Stacey MHSc. FACHE, FCCHSE

Overview
Research ethics review of clinical trials of new drugs is conventionally done on an institution-by-institution basis. Centralized ethics review offers potential efficiency, quality and consistency of review; however, it limits local REB/IRB authority and requires delegation of risk management activities. Previous attempts at centralization have been successful but of limited generalizability (NCI) or unsuccessful. We proposed a research ethics board for multi-centre trials in Ontario, addressing disparate needs of a heterogeneous group of cancer centres.

Methods
With support from the Ontario Cancer Research Network, a meeting was convened in June, 2002 of representatives of all 10 cancer centres in Ontario, 1 REB/IRB representative and 1 clinical investigator from each, in an attempt to achieve consensus. The proceedings of that meeting were distilled into a business plan for an Ontario Cancer Research Ethics Board (OCREB).

Results
In December 2003, the Ontario Cancer Research Ethics Board was launched with broad representation from a patient perspective and members with specific expertise recruited throughout the province. Member sites are able to utilize either the facilitated review option or the board of record option. Benefits are realized by investigators, local REB/IRBs, sponsors and study participants.
Parental Understanding of HIPAA in the Emergency Department

Authors: S.J. Cico, MD; E. Vogeley, MD; B. Doyle, PhD; J. Innocent, JD

Overview
With the passage of the Health Insurance Portability and Accountability Act, or HIPAA, which took effect in April 2003, covered entities were mandated to enact methods for communicating the purpose impact of HIPAA on individual patient rights. Here, we describe the results of a pilot study designed to assess the efficacy of HIPAA information transfer using a standard booklet given to parents/caregivers of pediatric patients presenting to the Fast Track at the Children's Hospital of Pittsburgh, part of the Emergency Department at an urban, tertiary care teaching hospital. A short, 21-item questionnaire (9 items of which are applicable to this study) was given to all parents and caregivers presenting with their child between 06 October and 02 November 2003. Six of the 9 items asked the parent to answer general questions regarding HIPAA, and the remaining 3 questions asked if the parent was familiar with HIPAA legislation; if they had received the HIPAA booklet at that or a previous visit; and whether or not they had read and understood the provided information.

A total of 329 questionnaires were distributed to unselected parents by the registration clerk and 206 were anonymously returned (62.6%). One hundred sixty-two of the parents reported that they had heard of HIPAA (79%), and of these 83 (51%), 59 (31%) and 29 (18%) reported that they received HIPAA information on the visit day, on a previous visit or had never received the information. Forty-four (21%) respondents reported that they had not heard of HIPAA and the respective distribution was 11 (25%), 1 (2%) and 32 (73%).

Twenty-four (10%) of the questionnaires were incomplete with respect to the 6 HIPAA knowledge questions (avg. number of persons with missing values = 20.1+1.1). The 182 questionnaires with more complete information were assigned to one of three subgroups: SG1 - persons reporting receiving and understanding the contents of the information package, SG2 - persons reporting receiving but not reading/understanding the information and SG3 (control) - persons reporting not receiving the information. The Table summarizes the percent correct responses to the 6 HIPAA knowledge questions for these groups and the probability of a correct response by chance.

<table>
<thead>
<tr>
<th>TABLE I - PERCENTAGE CORRECT RESPONSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4</td>
</tr>
<tr>
<td>SG1</td>
</tr>
<tr>
<td>SG2</td>
</tr>
<tr>
<td>SG3</td>
</tr>
<tr>
<td>Chance*</td>
</tr>
</tbody>
</table>

Q4: Year passed - 5 choices
Q5: Purpose of act - 5 choices
Q6: Covered Entities - 5 choices
Q7: Right to review medical records upon request: Y/N -Yes
Q8: Right to receive copies of medical records for free: Y/N - No
Q9: Right to limit access to medical records: Y/N - Yes.

*Random Answers (percentage)

These data show that while the majority of parents presenting with their child to the Fast Track reported being aware of the HIPAA legislation, this was not reflected in their knowledge of the specifics of the act
(e.g. year passed, purpose, covered entities, and parent/patient rights under HIPAA). Distribution of the information related to HIPAA was incomplete for patients presenting to the Fast Track; the importance of reading the information booklet was not communicated; and parent comprehension of the presented information was low, even in those who reported good understanding.

The results of this preliminary survey suggest that current methods to acquaint parents/patients with HIPAA are not efficient and do not satisfactorily address the parent/patient educational needs with respect to understanding their rights under the law. In future studies, we plan to evaluate methods to increase the transfer of information to parents/patients regarding their rights under HIPAA and to explore which areas of privacy parents/patients consider to be most important and in whom they have trust with the security of their protected health information.
Patient’s Consent for Donating Leftover Tissues in Singapore
Authors: Tuck Wai Chan, BSc; Siew Meng Chong, MD; Kok Onn Lee, MD

Background
Singapore inherited a health system and a legal system based on the British model, but has in recent years been increasingly influenced by US-style medical/patient attitudes on their rights over their tissues. In view of the Alder Hey publicity, it was decided to implement a consent form for all leftover tissue in our hospital in April 2002.

In the consent form, the patient is asked if he/she would agree to allow the remainder of any tissue not required for diagnosis to be used for medical research, education and study purposes. The patient is also informed that only excess tissue that remains after all necessary medical tests are completed will be used, and no extra tissue will be removed. An explanation, in the form of a Patient Information Sheet, is given to the patient that in the course of many procedures, tissue may be removed as part of the surgical procedure, and these tissues would otherwise be discarded if not required for diagnostic purposes. With the introduction of this consent form, we discovered that first it was necessary to have a tracking system to link the consent or non-consent with the individual tissue specimen in order to follow the patients’ wishes. This was achieved by the addition of an electronic ‘tag’ to the patient's identification number at the hospital, which is linked to all the patient's investigations results. With this in place, we had a quiet launch in March 2002.

The graph shows the level of positive consent over the last 6 months. There was initial resistance and this was discovered to be at the level of the junior doctors, who had not been adequately briefed and were not enthused with having to request (yet) another consent form to be filled by the patient. After a few meetings, the hospital staff (junior and senior) could see the importance of this new development for the purposes of medical research and education. As the graph shows, the level of positive responses then climbed steadily and has now reached a plateau of 80%.

We feel that this is a good result within 6 months, and other hospitals in Singapore will be implementing this consent request in the near future. Other hospitals in Singapore were persuaded that if this is possible for a tertiary hospital like National University Hospital, the other general and community hospitals might also be able to seek consent from patients for use of their tissues.
Primary Reviewer Assignment and its Impact on IRB Approval: Experience at One Medical Center  
Authors: Roberto A. Dominguez, MD; Daniel J. Feaster, PhD; Norman H. Altman, VMD

Objective
Most IRBs at major educational institutions use a primary reviewer model to triage "new" submissions. The objective of this study was to explore this model and correlate primary reviewer assignment to IRB adjudication.

Methods
These findings are part of a larger study where we attempted to find variables to justify a "pre-IRB" review model. The study sample consisted of all "new" submissions placed for convened biomedical IRB review at the University of Miami (UM) over a one-year period (10-01-01 to 09-30-02). During this period, UM had two medical IRBs (A & B). Materials reviewed included the minutes from 52 meetings, the IRB-specific research protocol forms, and other documents. UM uses a primary reviewer assignment model. Prior to IRB review, "new" proposals are assigned primary as well as secondary reviewers by the committee's administrator. This report will only focus on correlations made based on primary reviewer assignment.

Results
The two biomedical IRBs were similar in all major variables explored. These included membership, number of "new" submissions reviewed (A=242, B=241), and rate of proposals initially approved (A=52.9%, B=53.1%). The rate of approval by department was highly variable. When departments that submitted fewer than eight protocols are excluded, the initial approval rate by department ranged from 5.9% to 88.9%.

Understandably, most "new" proposals had a primary reviewer assigned from the same clinical department as the principal investigator (64.9%). Protocols with a primary reviewer from the same department were more likely to be initially approved (58.0%) than protocols where the primary reviewer was from a different department (44.4%) (p<.005). Proposals with a primary reviewer from a different department (23.6%) were more likely to be disapproved ("rejected") than those for whom the primary reviewer was from the same department (13.6%). This comparison just missed statistical significance (p<.06). Interestingly, protocols that identified external funding were significantly more likely to be assigned a reviewer from the same department (73.5%) than were protocols that did not identify external funding (47.8%) (p<.001).

Conclusions
A logical interpretation of the results is that having a reviewer familiar with the "science" of a proposal may be a factor in determining favorable adjudication. However, there may be other factors. The authors suspect that a primary reviewer from the same department is more likely to contact a departmental colleague to clarify aspects of an application prior to IRB review. Although this might appear to be a conflict of interest, the authors believe that IRB members can be helpful to their colleagues and at the same time take an objective stance in their review of proposals as IRB members.
Protecting Human Research Subjects in the NIH's Intramural Research Program: A Draft Instrument to Evaluate IRB Performance in Convened Meetings
Authors: D. Kalyan; L. Abbott; R. Wesley; A. Sandler; A. Wichman

Introduction
The centerpiece of federal regulations is Institutional Review Board (IRB) review of research from the perspective of protecting the rights and safeguarding the welfare of the human subjects. The Institute of Medicine, the DHHS's Inspector General and others recommend that IRBs strive regularly to improve their performance through formal self-evaluation. Most published studies of IRB performance examine only IRB records and procedures. However, paper audits only partially reflect IRBs' efforts to protect human subjects. It is in convened IRB meetings where all members have an opportunity to deliberate about ethical principles and regulatory requirements as they relate to the specific protocol under review. Yet little published work investigates IRBs' convened meetings. There is a need in the United States to evaluate IRBs' performances in satisfying minimal regulatory requirements and implementing the spirit of the regulations -- that research subjects are most likely to be protected if the research receives substantive review by an independent group of persons with diverse backgrounds.

Goals of this Pilot Project
The NIH Intramural Research Program (IRP) has a human subject protection program (HRPP) that includes 14 IRBs. NIH's Office of Human Subjects Research (OHSR) developed a draft instrument to evaluate NIH IRBs' performances in fulfilling regulatory requirements for the protection of human research subjects.

Methods
The draft evaluation instrument incorporates federal regulatory requirements and ethical guidelines. It has 3 sections. Section 1 asks evaluators to record their determinations of whether the IRB addressed the minimal regulatory requirements of 45 CFR 46.111 during its review of a protocol. Section 2 asks evaluators to judge on a 4-point Likert scale the thoroughness of the IRB's deliberations of each of the minimal regulatory requirements. Section 3 asks evaluators to provide their opinions on a 5-point Likert scale about some committee dynamics. At least 2 OHSR staff members attended 10 convened IRB meetings between June and August 2004. They used the draft instrument to evaluate an IRB's performance in the initial review of a protocol. Modifications to the instrument were made in an iterative process.

Results
We fulfilled the goal of this pilot project: to develop a draft evaluation instrument and use it to evaluate IRB review of protocols by several of NIH's 14 IRBs. Based on our experience, the draft instrument captures expert evaluators' objective and subjective observations of a convened IRB's performance in fulfilling minimal regulatory requirements for the protection of human research subjects.

Conclusions and Future Applications
We will use the instrument in all 14 IRP IRBs to: (1) evaluate their performances in meeting minimal regulatory requirements, (2) identify characteristics of successful convened meetings, and (3) educate NIH IRB members. The IRP HRPP strongly endorses the idea that the activities of its IRBs' convened meetings are critical to protecting human subjects. Evaluations of convened IRB meetings is one way to improve IRB effectiveness in protecting the rights and safeguarding the welfare of human research subjects. We think this draft instrument holds promise for promoting the protection of human subjects in the IRP. Because all IRBs are held to the same minimal regulatory requirements, the instrument may have potential for wide spread use in U.S. IRBs.
A Program to Enhance the Protection of Research Subjects in Zimbabwe

Author: Paul Ndebele

Background
The "Program to enhance the protection of human subjects of research in Zimbabwe" was conducted by the author under the auspices of the Johns Hopkins University Bioethics Institution in collaboration with the Medical Research Council of Zimbabwe (MRCZ) in partial fulfillment of the requirements of the Fogarty funded Bioethics Fellowship programme initiated in 2001 by the Johns Hopkins Bloomberg School of Public Health. The programme was based on available evidence indicating that there were some inadequacies in the human subjects protection system in Zimbabwe including evidence of some studies that had led to the deaths of research subjects.

Objectives
The main objective of the programme was to promote the ethical conduct of health research in Zimbabwe through the enhancement of the human subject protection system and practices. The programme was made up of various components (activities) and each component was related to a particular specific objective. The specific objectives included the following:

- To conduct a situational analysis of the current human subject protection system and practices in Zimbabwe.
- To update the MRCZ review and monitoring systems and procedures.
- To develop a comprehensive set of guidelines on the operations of IRBs.
- To conduct a workshop in order to sensitize researchers and IRB members on the ethical conduct of research and to apprise them about the new systems and procedures in place to ensure the protection of human subjects.
- To sensitize members of the community who are often the subjects of research on the difference between research and routine care and on their rights as subjects of research:
- To train and educate researchers and IRB members in the ethical conduct of research

Results/Observations
The committees were similar in all major variables explored including membership, number of new submissions reviewed (A=242, B=241), and rate of proposals initially approved (A=52.9%, B=53.9%). There was a robust statistical difference between the percentage of "trainee submissions" initially approved (39.6%) and those that did not identify a trainee (58.7%) (?2(1)=13.56, p<.0003). Of those proposals that were initially not approved (either deferred pending clarification ("tabled") or disapproved ("rejected")), 29.6% of those including a trainee were outright rejected in contrast to only 11.1% without a trainee (?2(1)=10.93, p<.001).

Considering all 483 submissions, those that identified external funding were more likely to be initially approved (64.9%) (?2(1)=93.12, p<.0001). Funding also seemed to influence the trainee and initial approval interaction. Approval rates for funded proposals were similar with trainees (63.5%) and without (65.2%). However, for proposals without funding the rate of initial approval with trainees (24.4%) was less than without trainees (37.8%, ?2(1)=2.85, p<.10). Of proposals that identified funding and listed no trainees, 7.5% were rejected. Of those without funding and with trainees 17.6% were rejected.
QA/QI of the Informed Consent Process Using Patient Satisfaction Surveys
Authors: Karen Marie Sheldon, CIM, CIP; Denise Castonguay, RN; Robin McInnis

Background
There has been much scrutiny in the last few years surrounding informed consent, both as a document and a process, and the best way to evaluate its effectiveness. There have been studies concerning readability and grade levels using the Flesch-Kincaid scales. New processes have been developed to audit the consent document and to evaluate the consent process through observational audits. However, we questioned whether or not these improvements have really contributed to the patients' understanding of the research, their involvement in the research, and their satisfaction with the overall experience.

Methods
Five studies of varying degrees of risk and actively enrolling patients were selected. From July 2003-July 2004, surveys were mailed to 172 patients asking them to rate their experience on various aspects of the informed consent process using a five-point scale ranging from "definitely agree" to "definitely disagree". The survey consisted of 14 statements, including: "The person who asked me to take part in the study explained the reason for the study"; "I understood what would take place in the study and how it might affect me"; "I was given enough time to read the consent form"; "I was given the choice to take the consent form home and talk it over with my family, friends, health care provider, or others"; and "I was informed that at any time during the course of the study I could make the decision not to continue". To make sure that patients were reading the statements versus just checking boxes down the line, a spot check was implemented by adding one statement written more negatively: "I felt pressured to take part in the study." With this question, we would want to see "definitely disagree". The back page of the questionnaire provided space for individual comments. The patients were also asked to provide a name and telephone number if they did not mind being contacted for clarification on their responses if needed. Postage-paid envelopes were provided for their convenience.

Negative responses of "disagree" or "definitely disagree" were followed up with a phone call if the patient provided a name and phone number. A patient complaint intake form was used to document the conversation and resolution of the problem. Likewise, a response of "definitely agree" or "agree" to the negative spot-check question was followed up with a phone call and documented.

Results
A total of 106 surveys were completed and returned, a response rate of 62%. Overall, respondent satisfaction of the informed consent process as a whole was: 75% very satisfied, 20% satisfied, 3% neutral, 1% dissatisfied, and <1% very dissatisfied.

Conclusions
Responses to the survey were helpful in identifying areas in the informed consent process needing improvement. Patients who received follow up phone calls for clarification on their responses or comments appreciated the fact that the surveys were actually being read and that something was being done with the information provided. Study staff assigned to obtaining informed consent were educated on the improvement measures to be implemented and were provided clarification as necessary. Areas of improvement for the questionnaires and complaint intake forms were also identified. Once these improvements are put into place, the survey will be expanded to include other active protocols.
Recruiting IRB Committee Members
Authors: Philip A. Ludbrook, MD; Patricia M. Scannell, BA, CIP; Deb Thompson; Keisha Buckley; Sarah Frankel, PhD and Melissa Torres, MSW

Background
There are current discussions that suggest that IRBs should be composed of more unaffiliated members as they are the individuals representing the research participants’ perspectives. However, IRBs are still mandated to have “at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.” (45 CFR 46.107) Therefore, IRB membership must be balanced. The challenge comes when trying to develop and maintain that balance between physician scientists, other scientists, and unaffiliated members so that the committee has enough expertise to review the protocols and also enough representation to ensure that a research participant's perspective is considered.

Overview of the Project
In recruiting and retaining its 250 members, the HSC has developed strategies for targeting and recruiting its membership. The purpose of this poster is to provide institutions with guidance regarding strategies that can be used by any committee when recruiting new members, developing a balance between reviewers, and increasing retention. A special emphasis will be placed on recruiting and retaining unaffiliated members, as IRBs are exploring the possibility of increasing their “lay membership” to 25% or more.

Recruitment strategies include:

- Presentations at Mini-Med School and community organizations such as Oasis
- Contacting the Rabbinical Association, Catholic Diocese, and other religious organizations
- Efforts to reach minority communities
- Use of research databases
- Letter from the Dean, School of Medicine encouraging new members to join
- Identifying number of protocols submitted from a given area and requesting members from that area in proportion to number of submissions
- Educational events
- Word of mouth

Retention efforts include:

- Annual recognition dinner
- Offering a variety of on-going education for members
- Letter from Dean, School of Medicine thanking IRB members for serving

Conclusions/Applications
Feedback has been positive from IRB members and HSC staff concerning the recruitment and retention of IRB members. Developing and maintaining a balance between physician scientists, other scientists, and unaffiliated members so that the committee has enough expertise to review the protocols and also enough representation to ensure that a research participant's perspective is considered a continual process.
Setting up an IRB in a Developing Country - The NMIMR Experience
Authors: Okyere Boateng, Rev. Dr. S. Ayete-Nyampong, Prof. D. Ofori-Adjei, Dr. G. E. Armah

Background
The Noguchi Memorial Institute for Medical Research is a constituent of the College of Health Sciences (CHS), University of Ghana, Legon with a mandate to research into infectious and communicable diseases, nutrition and diseases of Public Health importance. The Institute collaborates with various national and international organisations e.g. WHO/TDR, NIH, JICA, UNICEF etc. As a result of increasing research collaborations and the need to protect research participants an Institutional Review Board was formally established in the Institute to review, evaluate and take decisions on the ethical merits of NMIMR research protocols as well as to ensure and guarantee the rights, dignity, safety and protection of all individuals and communities that participate in NMIMR research activities. Prior to that it was an ad hoc committee constituted to review protocols on a case by case basis. Currently the IRB is responsible for five other health-related faculties in the CHS.

Methods
The IRB is composed of nine voting and two non-voting members and is chaired by a member drawn from the community representation. The initial set up process involved the recruitment of new members, training them through workshops, seminars, conferences at the national and international levels and the sensitisation of the College/University community in the essence of review of proposals involving human participants.

Results
What has been achieved is the building of confidence in the Board and this is due to the high level of expertise exhibited by the Board through the review process and the excellent documentation of IRB records. The Board is sharing its experience by helping to establish other IRBs and providing support to other research centres. A total of 107 protocols had been reviewed over the last five years with thirty-four being behavioural and the rest biomedical with about twenty-five percent of the protocols coming from outside the Institute. The major shortcomings observed in the review process include inadequate administrative support and finance. Some of the issues addressed during the review process cover conflicts of interest, culture, language, ethnicity, poverty and low literacy levels of the study population.

Conclusions
In conclusion the performance of the Board and its activities has triggered a renewed interest in ethics in health research hence the formation of the Ghana Bioethics Initiative, the establishment of an IRB at the Health Research Unit of the Ministry of Health and the initiation of the process to establish other IRBs.
A Survey of Clinical Research Investigators and Clinical Research Coordinators About the Process of Informed Consent
Authors: Neil J. Farber, MD, FACP, Jerry Castellano, PharmD, Janet Leary-Prowse, MS Ed

Background
Little research has been conducted on the actual process of informed consent in clinical research. Most studies have asked general questions rather than targeting specific aspects of the informed consent process. The purpose of this study therefore is to survey investigators and coordinators about their views on the conduct of the informed consent process in clinical trials.

Methods
A survey asked respondents about their activities involving the informed consent process in clinical research. The survey was pre-tested among IRB members at Christiana Care Health System for face and content validity. Thereafter, the survey was sent to all research coordinators and clinician investigators at Christiana Care Health System and the A.I. DuPont Children's Hospital. All non-respondents were sent a second mailing and then contacted via e-mail. In addition to descriptive data, the effects of the demographic data on respondents' actions involving the informed consent process were analyzed via multiple logistic regression.

Results
Of 250 individuals that received the survey, 135 (54%) returned completed questionnaires, and 89 (66%) of these respondents were involved in obtaining informed consent and make up the study group. Most respondents (54%) spend 30 minutes or less in the informed consent process, and only 47% check the understanding of the patient. A majority of respondents encourage questions (95%), encourage patients to take home the consent form (67%), and encourage discussion with family or friends (84%), but only 27% felt that the primary purpose of clinical research was to benefit future patients, and 36% would encourage subjects to enter a clinical trial. Respondents with training in the informed consent process and those having spent 12 or more years in research spent more time on average than those respondents who had no training or who spent less time in clinical research (p = 0.01; p = .003). Clinical research coordinators were more likely than clinician investigators to encourage patients to take home the informed consent form (p = 0.044) and to leave the decision to enter the trial up to the patient (p = 0.022).

Conclusions
Although coordinators and investigators generally encourage patients to be involved in the informed consent process in clinical research, they spent little time informing patients and to some degree attempt to pressure patients to enter trials while refraining from checking patients’ understanding of the research. Training and experience may have a positive impact on the informed consent process. Investigators and IRBs should ensure adequate training of investigators and coordinators, and the informed consent process should be left to the most experienced individuals with the most time available, often the research coordinators.
The IRB Role in Protecting Human Embryos Created Through In Vitro Fertilization

Author: Darren McDaniel, MS

Background
The demand in the United States for In Vitro Diagnostic (IVD) technologies is expected to reach $12.7 billion by the year 2005 (Freedonia Group, 2001). Louise Brown, born in England in 1978, was the first "test tube" baby. Ms. Brown was conceived by a procedure called In Vitro Fertilization (IVF). As new technologies, such as pre-implantation genetic diagnosis (PGD), are developed and refined, research studies strive to keep pace. Since research studies are governed by federal regulations and foundational ethical principles, the purpose of this abstract is to tackle an area that has few federal regulations and little guidance within the scientific literature; that is, how should an IRB grapple with the ethical complexities associated with IVF.

The IRB Review
This session will focus upon case studies of actual IRB reviews of IVF protocols and decisions made to protect human embryos by intrinsically considering current medical literature, Belmont principles, and federal regulations.

- **Science**
  The board must ensure that each research study falls in line with general medical knowledge and, in the case of something investigational, with well thought out, empirical research that allows for a valid hypothesis to be tested. Pre-Implantation Genetic Diagnosis (PGD) involves performing a biopsy on a live human embryo. Before diving into ethical issues surrounding PGD, this session will first consider what is currently known (scientifically) about a human embryo.

- **Federal Regulations**
  45 CFR 46.204(d) requires all research involving human in vitro fertilization or embryo transfer to be reviewed by a national ethics advisory board before it can be funded by the DHHS. 21 CFR 809.3(a) governs in vitro diagnostic (IVD) device studies that employ products intended for use in the collection, preparation, and examination of specimens taken from the human body. We will discuss the IRBs interpretation of the federal regulations as it pertains to various protocols involving IVF and human embryos.

- **Key Ethical Principles**
  Given the minimal regulatory guidelines noted above, IRBs are often required to rely on the Belmont Report, which contains the ethical guidelines for the protection of human research subjects.
  
  The very first ethical principle contained in the Belmont Report is "Respect for Persons". This ethical principle calls for IRBs to protect persons with diminished autonomy. The report states that "not every human being is capable of self-determination...Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated." (FDA, 1998). This session will address how an IRB reviews IVF/embryo protocols in light of "Respect for Persons."

Conclusions
In the years to come, with advancing In Vitro Diagnostic (IVD) technologies and the billions of dollars behind them, each IVD study needs to be reviewed by an IRB. The IRB needs to apply scientific knowledge with federal regulations and common-sense application of the ethical guidelines to make good decisions about the ethics of each IVD research study. The hope is that this session, with IRB case studies, will assist IRB members, IRB staff, regulators and researchers in thinking about the need for thorough IRB review and oversight of all protocols involving IVF and human embryo.
The Nonscientist's Review Process of a Biomedical Protocol
Authors: Karen J. Schwenzer, MD, Susie R. Hoffman, RN, BSN, CIP

Overview
Federal regulations require at least one voting member whose primary concerns are in nonscientific areas to be present at full IRB meetings. The role of nonscientist members on the IRB is not described in the regulations.

Prior to 2003, the Human Investigation Committee, the sole biomedical IRB at the University of Virginia, provided each new protocol with one primary review, with the chair providing a secondary review. Attempts were made to match an appropriate biomedical protocol to the backgrounds of our nonscientist members; however, it was hypothesized that many of our nonscientist members were having difficulty reviewing complex biomedical protocols. To address this, we revised the role of our nonscientist members in 2003.

The revised review process provides each new protocol with two primary reviews; one from a member with a scientific background and a second review from one of our nonscientist members. The nonscientist members were told to direct their attention to review of the consent form with particular regard to readability, to the description of the investigational procedures, anticipated benefits, and probable risks, and to determine whether or not they would participate if they were eligible for the study. A separate review checklist was developed for the nonscientist member.

In order to assess the utility of our revised review process and the satisfaction of the nonscientist members with it, we surveyed the nonscientist members who participated in the former and the revised review processes. After approval from the social and behavioral sciences IRB and written informed consent, nonscientist members received an email questionnaire. Data was collected anonymously and is reported in a descriptive manner.

In 2003, the HIC consisted of 22 full-time members, including 7 nonscientist members who participated in the former and the revised review processes. Three completed surveys were returned for analysis. In general, the completed surveys indicated a favorable response to the revised process. All felt that it was better for the nonscientist members to review the consent form "written for nonscientist patients" than the entire protocol. All felt more comfortable giving oral presentations at the IRB meetings under the revised process. All felt appreciated by the scientist members under both systems, though "not as much as now!" under the revised process. All indicated a good experience working on the IRB. Two indicated that their biggest contribution was ensuring the consent is understandable. One indicated that they contributed "a different perspective."

The Federal regulations require nonscientist members on IRBs, however their role is not described. We hypothesized that our IRB's ability to protect human subjects involved in research could be improved if we changed the role of our nonscientist members. Our revised review process assigned a nonscientist member as a second primary reviewer to each new protocol, with focus on the consent form. We have found that utilizing two primary reviewers was easily incorporated into our structured approach to reviewing new protocols. The nonscientist members liked the revised review process, felt more comfortable giving oral presentations, and felt appreciated by the scientist members. We conclude that the revised review process is an excellent way to utilize nonscientist members on an IRB.
The Use of DSMBs in Clinical Research
Author: Nora Cavazos, MD

Background
According to the regulations: "In order to approve research...the IRB shall determine that risks to subjects are minimized" (CFR 56.111). DSMBs constitute an important safeguard for human research subjects participating in clinical trials. The objective of this presentation is to describe the type of studies that used DSMBs or similar monitoring committees and the general characteristics of the committees among clinical trial protocols reviewed by WIRB during 2003.

Methods
We examined all clinical intervention studies reviewed by our institution during 2003 in relation to the use of DSMBs by medical area, type of intervention, use of placebo or sham devices, and vulnerable populations. The general characteristics of the committees were also analyzed.

Results
Among the 1191 intervention research protocols reviewed by WIRB in 2003, about 22% used a data and/or safety monitoring committee by the name of DSMB or other similar denominations. Biotechnology research used DSMBs more frequently than studies with drugs and devices. Pulmonology and cardiology research used DSMBs more frequently than other specialties. In the areas of oncology, CNS research, and infectology, the use of placebo or sham devices was more frequently associated to the use of a DSMB. About 59% of the DSMBs were independent; 11% were not independent and the rest did not specify. The average number of members among the studies which mentioned this variable (n=144) was 3.5, ranging from 2 to 7. The frequency of meetings was often flexible depending on the achievement of recruitment or safety targets. Among 210 drug studies, 88 DSMBs (42%) reviewed efficacy interim analysis and included clearly defined stopping rules. Among 47 device studies, 7 (14%) DSMBs reviewed efficacy interim analysis and 12 (25.5%) had stopping rules. Many protocols did not include enough information about the DSMB, and in many cases, a DSMB seemed to be in place but was not mentioned.

Conclusions
1. The use of DSMBs in Clinical Research has increased in recent years.
2. Following FDA and NIH guidance, DSMBs are established for studies on high-risk interventions, usually comparative but not necessarily blinded.
3. More than a half of the DSMBs for drug studies and most DSMBs for device studies are established for safety purposes only.
4. IRBs require information about the characteristics and objectives of DSMBs.