Programmatic Poster Abstracts from the 2009 AER Conference: Navigating the Future Using the Belmont Compass

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360 Degrees of Human Subjects Protections in Community Engaged Research: A Proposed Taxonomy of Risks and Their Management

Authors: Lainie F. Ross MD, PhD; Alan Loup; Jeffrey R. Botkin, MD, MPH; Rhonda G. Kost, MD; George R. Smith, Jr., MPH; Robert Nelson, MD PhD; Sarah Gehlert, PhD

Background
In the 30 years since the Belmont Report, the role of the community in research has evolved and taken on greater moral significance. In contrast to prior focus on ‘bench to bedside’ research, investigators now seek to design research such that their findings will be as significant in patients from the real world as they were under highly controlled conditions. Such research is referred to as translational research, and spans a continuum from first clinical application, to real world outcomes. Increasingly translational research is performed with the active engagement of communities as collaborative partners with their own goals, values, beliefs and needs. Novel risks arise when communities become partners in research. Additional considerations, beyond those focused on the rights of the individual, are required to mitigate the potential impact that community partnerships and community-based research may have for those communities that participate.

Description of Program
Methods: A group of community researchers, community representatives, ethicists, and human protections experts was assembled, supported by an NCRR funded Clinical and Translational Science Award Administrative Supplement, to develop a vision and recommendations for “360 Degrees of Human Subjects Protection in Community Engaged Research”. Face to face meetings, a series of conference calls and writing workshops were conducted. Through iterative collaboration, a framework for the risks presented by community engaged research was defined, the implications explored, and development of appropriate safeguards discussed.

Results: A new taxonomy for risks in community research was developed, specifying the intersections of those at risk: 1) Individual, 2) Individual by Group association, and 3) Community, —with types of risk: 1) Process Risks to Well-being, 2) Outcome Risks to Well-being, and 3) Risks to Agency. Illustrative examples for each risk were developed and discussed. A human subjects protection (HSP) program for Community Engaged research must address 9 main ethical concerns: 1) minimizing risks; 2) reasonable benefit: risk ratio; 3) fair subject selection; 4) adequate monitoring; 5) ensuring informed consent; 6) ensuring privacy and confidentiality; 7) managing conflicts of interest; 8) addressing vulnerabilities; and 9) proper training in human subjects protections. These functions should be coordinated between the various entities that may serve to protect human subjects including-- the investigator, the Research Ethics Consultation, the Institutional Review Board, the Research Subject Advocate, the Data and Safety Monitoring Plan, and the Community Advisory or Oversight Board. Key questions were developed to ensure full consideration of each ethical concern by the HSP program, allowing individual sites to determine which entities are responsible for which issues. Some overlap was recommended in order that the process incorporated some checks and balances.

Limitations: The proposed taxonomy and recommendations have not yet been implemented. Next Steps: To develop an implementation plan, and evaluation method for testing the effectiveness of the new taxonomy in anticipating and reducing risks to communities.
A Brief Description Of The Current Status Of Structure And Functions Of 15 Research Ethics Committees, Which Are Members Of The Peruvian Network Of Research Ethics Committees
Authors: A. Roxana Lescano; Sixto Sánchez; Estela Quiroz; Jose Tantaleán; Juan L. Lema; Alfredo Benavides; Julio C. Alfaro; Manuel Ruillón; Hillary Creed; Salomón Zavala; Andres G. Lescano

Background
In 2006, the Peruvian Ministry of Health enacted the Regulation for Clinical Trials which required the Registration of Research Ethics Committees (RECs) that would be involved in reviewing and approving clinical trials to be conducted in Peru. As part of this process and in order to comply with the registration process, RECs need to submit a request for registration, a copy of their letter of creation issued by their organization, a copy of their roster, their regulation and operating manual. Additionally, in order to avoid a duplication of registrations, this same process was used toward becoming members of the Peruvian IRB Network. Between 2007 and 2008, a total of 24 RECs complied with the registration requirement with the OGITT. The objective of this review was to perform a situational diagnosis of the member RECs of the National Network of Research Ethics Committee, to assess their regulations and operating manuals and to show the training activities the REDCEI members participated in between 2005 and 2008.

Description of Research
After the enactment of the 2006 and 2007 Peruvian Regulations for Clinical Trials, the Peruvian National Institute of Health (INS) and the Peruvian Network of Research Ethics Committees (RECs) launched several strategies to strengthen the review and conduct of clinical trials. A key part of these efforts was the registration of research ethics committees, which entailed the submission of REC rosters, updating policies and procedures, and meeting training requirements stipulated in the National Regulation. We conducted a qualitative and quantitative evaluation to assess compliance with the Peruvian regulations among REC members of the Peruvian REC Network. Fifteen (63%) of the 24 REC members of the REC network were evaluated and they showed great progress toward compliance with the Clinical Trials regulations regarding the availability of manuals and standardized operating procedures. All RECs had institutional regulations and operating manuals, a direct requirement of the 2006 Clinical Trials Regulations and the REC registration process enforced by the INS. Also, twelve surveyed RECs (80%) were aware of their obligation to maintain adequate files of their research documents and ten (67%) recognized their obligation to monitor approved studies. However, the evaluation also highlighted challenges and areas in need for improvement. Most RECs lacked the minimal infrastructure for confidential storage and management of research documents, and only 26% had full-time, trained employees for this purpose. RECs also lacked funding to conduct much-needed monitoring activities of approved research protocols using dedicated personnel. Research organizations need to guarantee continued institutional efforts to provide RECs with the minimal logistical support they require. After meeting minimal logistic requirements and baseline training for members and support personnel, RECs must urgently start implementing a monitoring system for previously approved studies. Securing trained and dedicated REC staff for quality control and monitoring is an essential component to conduct REC duties effectively. Without adequate staffing, RECs will not be able to properly support the conduct of ethical and high-quality research. The Peruvian IRB Network has been a key strategy to strengthen REC members by providing training, technical assistance, and monitoring and evaluation of their performance.

Additional Information
As a result of the enactment of the Peruvian Regulation for Clinical Trials in 2007, the Peruvian National Institute of Health in coordination with the Peruvian Research Ethics Committee Network (REDCEI), initiated the registration of research ethics committees (RECs), as one of the key strategies to strengthen the clinical trial system in Peru. This registration entailed the submission of REC rosters, updating policies and procedures, and meeting training requirements stipulated in the National Regulation. We show the results from a qualitative and a quantitative assessment aimed at determining the capabilities of 15 respondents out of the 24 REC (62.5%) members of the REDCEI. Improved compliance with the
Peruvian regulations and highlighted challenges and areas in need for improvement were among the results obtained from this assessment.
A Model for Human Subjects Protections and Research Compliance
Authors: Lu Ellen Davie, BSN, RN, CIP; Barbara Gibson, BSN, RN, CIP; Angela Oatridge, PhD, CIP

Background
The impetus for the current human research protection program model is to develop and maintain a highly compliant research program within the institution and its research community, in light of the continuous growth and complexity of human subjects research. Increases in collaborated research between internal departments and outside institutions are an increasing trend, which brings the potential for increased disparity among the groups. The goal of the program is to provide a model that allows and promotes the interlocking and engagement of Vanderbilt researchers within and between departments to overcome communication silos and to establish a comprehensive compliance program that maintains its independence from the institution.

Description of Program
The program consists of multiple components: Technology Transfer; Institutional Biosafety Committee; Division of Sponsored Research; VU and VUMC Office of Compliance; University Conflicts Committee; Risk Management; Research Optimization Committee; Center for Patient and Professional Advocacy; Research Billing Compliance; Grants and Contracts Management; Vanderbilt Institute for Clinical and Translational Research; IRB Optimization Committee; Research Support Services; Research Advocacy Program; HIPAA Privacy Board for Research; HSRC/RDRC; IRB Health Science and Behavioral Committees; Process Improvement Team; Medical Informatics Services and StarBRITE.

The success of the AAHRP accredited program is measured through federal and AAHRPP reviews, internal audits and quality improvement mechanisms, and feedback from the research community.

Future suggestions for internal program development include developing a more efficient means of communicating conflicts of interest to the IRB, exploration into the use of alternative review models for new study submissions, development of a model for increasing community education and involvement in research, development of a model for improving the consenting process, and development of an outreach program to immediate affiliates. We suggest the broad integration of the IRB throughout the institution to maintain a bidirectional awareness of current events, thus creating a culture for research compliance and human subjects’ protection.

Additional Information
A description of each of the individual components will be expounded upon in the poster. The components will be flow charted to show how they are integrated institutionally.
A Model of Collaboration for the Education & Continued Informed Consent for Participants in Schizophrenia Research
Authors: Katherine J. Whorton, LCSW-C; Denise Niner, LICSW

Background
The NIMH conducts research with adults with schizophrenia. We expect capacity to change during research due to the nature of the illness (e.g. cognitive difficulties) as well as medication changes including the possibility of being off antipsychotics. The schizophrenia research team and the Human Subjects Protection Unit (HSPU), a group independent of the researchers, have collaborated to develop a program to ensure ongoing education and consent capacity for potentially vulnerable research participants.

Description of Program
These are inpatient, more than minimal risk studies with no prospect of benefit requiring a 3-6 month length of stay. All protocols require participants have capacity to provide informed consent throughout study participation as determined by the HSPU and do not allow for surrogate consent. There are two types of studies:
1) One requires subjects be medication free
2) Three studies add on an investigational medication to subject’s current regimen.

There are two parts to this program:
1) Education of the subject by the research team
2) Assessment of capacity and monitoring of informed consent by HSPU Research Team Role
   - Pre-admission, MSW gathers psychiatric records to screen for eligibility;
   - Ongoing education of subjects and family members;
   - Develop individualized, 1:1 education plans based on learning style and participant needs;
   - Ongoing evaluation of subject capacity and coordination with research team, families and HSPU HSPU Role;
   - Consent monitoring throughout inpatient stay;
   - Independent protocol specific capacity assessment using a modified MACCAT-CR - Participant education group;
   - Participation in interdisciplinary rounds;
   - Consultants to research team regarding changes in clinical status, consent capacity and continued research participation;

Program Evaluation: Review of statistics including percentage of subjects who:
- pass capacity assessment
- require further education
- pass with further education
- have capacity for a lower risk study
- don’t participate due to lack of capacity
- complete a protocol
- are unable to complete a protocol due to a change in capacity.

The poster will review statistical data including pre/post morbid IQ, age and sex, decreased costs related to travel, staff time, length of stay and other research resources by screening out subjects earlier in the process.

Future Use: Apply to other psychiatric and medical populations throughout the NIH Suggestions for implementation at other sites; Program can be templated to other research venues using established resources.
A Systematic Approach to Tracking Regulatory Data
Authors: Elizabeth O'Connell, RN, BSN; Sarah Lein, MS; N. Beth Ragan; Pam Schwingl, PhD

Background
Many research projects require regulatory approval at multiple institutions. Principal investigators and study staff must track multiple review dates and maintain a complete history of these dates at the project level. Keeping track of submission due dates, actual submission dates, and approval dates for each protocol at multiple institutions can be labor intensive. To address the need for a systematic approach to tracking the regulatory process for multiple projects and multiple institutions, Social & Scientific Systems (SSS) working in support of the Epidemiology Branch at the National Institute of Environmental Health Sciences (NIEHS), designed a multi-functional Regulatory Database.

Description of Program
The Regulatory Database is managed by the IRB Administrator of the Public Health Research Center at SSS and regularly populated with data as it becomes available. For all projects supported by SSS, the names of institutions and investigators, review type required, initial protocol submission dates, annual review dates, amendment submission dates and all corresponding approval dates are entered. In addition, the institution IRB meeting dates, OMB submissions and approvals, and details of any Material Transfer Agreements associated with a project are entered.

Using these data, the system calculates all of the upcoming regulatory due dates; automatically notifies study staff via email at regular repeated fixed intervals preceding the particular due date for their assigned protocol; tracks the actual submission dates over the life of the protocol; tracks receipt and location of submission and approval documents; and identifies gaps when data are missing. The system was developed using Microsoft Access 2003 and Visual Basic. The pass-worded master database resides on a network, with a copy of the front end of the database installed on each user’s computer with read-only permission, enabling them to parameterize, print and/or export reports and view the multi-tabbed data form. Via Microsoft’s Smart Tags, users can easily contact investigators, study managers and database developers with the click of a button, from within the database. Internal VBA code is automatically run each week, generating email notifications of upcoming due dates to study managers. These are sent via SMTP and triggered by an internal database macro called by Microsoft’s Scheduled Tasks.

The implementation of the database has resulted in a streamlined and predictable generation of appropriate regulatory actions. Use of the database has resulted in a more efficient way of tracking the history as well as informing of upcoming regulatory activities for the investigators and study managers.
A Web-Based Community Consultation Data Management System for Large Multi-Center EFIC Trials
Authors: Wenle Zhao; Keith Pauls; Catherine Dillon; Valerie Durkalski; Yuko Palesch

Background
The Code of Federal Regulations Part 50.24 (Protection of Human Subjects) allows for subjects to be enrolled in EFIC studies provided that community consultation and public disclosure activities are properly conducted and approved by local IRBs prior to study start. Management and documentation of community consultation efforts in large multi-center trials pose special challenges due to the collection of a vast amount of data across participating centers, the lack of site experience in community consultation which requires Human Subject Protection Coordinators (HSPCs) to closely supervise and direct these efforts and the difficulty in standardizing the data due to open-ended and unpredictable questions and responses. A web-based community consultation management system is highly efficient, expedites the collection, coding, review and reporting of such data and can be easily implemented.

Description of Program
A web-based data management module was developed within a Clinical Trial Management System (CTMS) to support the data management and project coordination of community consultation (CC) activities in the Neurological Emergencies Treatment Trial (NETT) network which conducts trials approved for Exception from Informed Consent (EFIC) in 17 hub centers and more than 200 spoke hospitals in the US. Currently, 2 EFIC trials are being conducted in NETT: the Rapid Anticonvulsant Medication Prior to Arrival Trial (RAMPART), and the Progesterone for Traumatic Brain Injury: Experimental Clinical Treatment Trial (ProTECT III). The Code of Federal Regulations Part 50.24 (Protection of Human Subjects) allows for subjects to be enrolled in EFIC studies provided that CC and public disclosure process are reviewed and approved by local IRBs prior to study start. For these two trials, it is anticipated that a total of 500 CC events will be conducted once all hubs meet their local IRB requirements which will result in the collection of approximately 6000 open ended and 3000 close ended questions. Management and documentation of these activities pose special challenges due to the collection of a vast amount of data across participating centers, the lack of site experience in community consultation which requires Human Subject Protection Coordinators (HSPCs) to closely supervise and direct these efforts and the difficulty in standardizing the data due to open-ended and unpredictable questions and responses.

To address these issues, we integrated a CC module into the NETT’s already existing CTMS. This system allows for direct data entry of CC data using a user-friendly interface. As new free text questions raised during the events are data entered, they are coded centrally by HSPCs. These coded questions are then added to a question bank to be used by study coordinators for subsequent events across centers. The progressive formulation of the CC question bank and central reconciliation of the data allows for high quality data analysis and interpretation of the information. Using such a system, the CC data is available in real time via customizable reports which can be generated and submitted to IRBs and other regulatory authorities as needed. Our experience has shown that using such software is highly efficient, expedites the collection, coding, review and reporting of CC data across the network and can be easily implemented at sites external to the network.
Additional Protections for Subject with Impaired Decision-Making Abilities—The University of Michigan Program
Authors: Belinda Adamson, CIP; Lee A. Booze-Battle, CIP; June Insco, CIP

Background
The Belmont report notes that not every human being is capable of self-determination. Some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect the incapacitated requires protecting them while their decision-making capacity is inadequate. These subjects encompass those with a broad spectrum of conditions such as persons in shock, persons with severe mental retardation since birth, persons with conditions that cause fluctuating capacity, persons with progressively diminishing capacity (e.g. Alzheimer’s), and persons with sudden onset, permanent or temporary impairment (e.g. stroke). Federal Regulations do not set out specific requirements for review and approval of research involving these subject populations as they do for children, neonates, fetuses, and prisoners.

Description of Program
Institutions need written policies that protect subjects with impaired decision-making capacity, promote consistent IRB review, and guide investigators in designing their protocols. Description of Program: The University of Michigan outlines in our Human Research Protection Program (HRPP) Operations Manual the policy for research involving this population. Approval requirements mirror the requirements set forth in 45 CFR 46 subpart D, including assent requirements, with the following exceptions:

- If the scientific question can be answered without including these populations and there is no potential of direct benefit, these subjects cannot be included in the research unless there are compelling reasons for their inclusion.
- Protocols must include a description of the plans for appropriate assessment of subjects’ initial and/or on-going capacity to consent and/or assent.
- We have no 406 equivalent in that, if the research presents no prospect of direct benefit and the risk is greater than minimal, even if it is a minor increase over minimal, the IRBs cannot approve the research until the Office of the Vice President for Research (OVPR) posts the study on the HRPP website, forms a review committee, reviews and approves the study.

The policy is posted on the HRPP website. IRB staff and members were informed of the policy, effective January 2008, via educational presentations at convened board meetings. Investigators were informed via web postings, articles in various campus news sources, and educational workshops offered quarterly.

Evaluation Method: Policy review will include considerations such as consistency in IRB review, investigators’ responses in regard to the assent requirements and OVPR review, and investigator compliance assessed through routine and for-cause audits.

Suggestions: Institutions should establish explicit policies for research involving subjects lacking decision making capacity.

Additional Information
Collection of the above information is a non-regulated activity not requiring IRB approval by regulations or UM’s institutional requirements.
An Essential Regulatory Compliance Tool for the Development of an Administrative Monitoring Plan
Authors: Wanda Quezada, CIP; Marion Olson, CIP; Evanna Thompson, MPH, CIP; Marci Montemayor, CIM; Martha Matza, MS, CIP, CIM

Background
Academic research departments should proactively develop an administrative research monitoring plan (ARMP) for human subjects protection to assure compliance prior to the identification of regulatory shortcomings. Departments need to be provided simple tools to devise a plan specific to their area of expertise. These tools need to be flexible to address different types of human subject programs and dynamic to allow for all phases of research projects. Additionally, the tools need to accommodate a comprehensive and detailed ARMP that includes a blueprint for how research will be conducted.

Description of Program
Creating a template for an administrative research monitoring plan provides a useful tool that Institutional Review Boards (IRBs) can offer to assist academic research departments. The development of an ARMP is vital to establishing continued compliance. For an ARMP to be effective and provide useful information, the department should consider the type of research being conducted by its investigators, the funding source of the research, and whether or not the study is already being monitored by a data safety and monitoring board or another external entity. The plan should begin with an assessment of the department’s research infrastructure, including a review of essential educational and training requirements for staff conducting the research, a description of available resources, and a method to periodically review those resources to assure that they are and remain adequate. The ARMP should also account for unique issues within the department and provide an outline of how they will be addressed. In order to assure the protection of human subjects, the monitoring plan should encompass: (1) procedures to enhance data integrity, (2) methods for ensuring quality data retention, (3) a process for continuous education of essential staff, (4) an internal departmental process for conducting and reporting random audits and (5) strategies for appropriate disclosure and management of conflicts of interest. Once the department has assimilated the necessary information, a customized ARMP can be designed.

Evaluation: A practical ARMP should include simple processes that can be easily adhered to. Once the plan is finalized, in-services should be held by senior research staff for all personnel engaged in research. Expectations for adherence to the plan should be outlined in a clear and concise manner, including possible ramifications if the plan is not followed. Auditing of the plan within the framework of ongoing research is necessary to ensure a department complies with the current requirements and has the appropriate required resources.

Suggestions: Institutions should assign the task of developing an ARMP to individuals with regulatory expertise in the human research protection program. An ARMP built using the appropriate tools would be well-organized and include the pre-defined requirements. Implementation of an ARMP can prevent regulatory quandaries and provide a method for handling unexpected compliance issues.
An Innovative Approach to Streamlining Research Review: The Joint IRB/CTRC Review Committee
Authors: Adina Lieberman, CIP; Emma Meagher, MD; Heather Emery; Tracy Ziolek, MS, CIP

Background
Historically, review by the Clinical and Translational Research Center (CTRC) and the IRB were conducted separately. This proved to be a cumbersome process for the investigator. The IRB and CTRC developed a joint review process to: (1) minimize investigator’s administrative burden by reducing the committee approvals needed; (2) decrease the amount of time for issuance of full IRB and CTRC approval; (3) prevent overlap and redundancies; (4) overall better utilize IRB and CTRC administrative resources to provide an efficient and succinct review process.

Description of Program
The CTRC was formed with the receipt of the Clinical and Translational Science Award (CTSA), an NIH Roadmap initiative, with a goal to provide the resources, environment, operations, and training to support and promote high-quality clinical and translational research. In the past, investigators who wanted to utilize CTRC resources were required to submit their protocols to both the CTRC council and the IRB. The IRB and CTRC worked together to establish a committee that considers the criteria for IRB approval and CTRC approval. The CTRC Directors worked closely with the IRB Administrator to develop a joint IRB/CTRC review process which provided a committee setting for the CTRC issues to be discussed while still acting as a forum to conduct IRB review per federal regulations. In addition, 6 CTRC reviewers were trained to serve as IRB members and integrated on to the Board.

Outcome: To date, 37 protocols, since November 2008, have been reviewed. Positive feedback has been received from the research community, noting that joint review has helped streamline the submission process. Recently, the CTRC and IRB met to further polish the joint review process.

Suggestions for future usage: The CTRC and IRB continue to work closely so that each side receives the necessary support. After one year, the IRB members will be asked to evaluate the success of the integration of the two committees; this feedback will be used to determine what improvements should be made to this joint process.

Suggestions for other sites: This process development may be useful for institutions that require submission to multiple review committees. The institution should consider feasibility and necessity of a combined review. It is suggested that the committees establish review responsibilities and financial support. It is also suggested that the members of each committee are trained to differentiate between review requirements so that the IRB members can smoothly transition over to participating in a joint review process.
An Ounce of Prevention: Undergraduate Workshops

Author: Lane Fischer

Background
Internal funding of undergraduate student research is very generous at BYU. Hundreds of undergraduate projects are funded each year. Two-thirds of the projects require IRB clearance before funds are released. Historically, many undergraduate proposals have been so poorly constructed that the IRB has been in the unenviable position to either deny proposals or endure cumbersome revisions. Students facing travel deadlines for international studies were particularly discomfited by denials or delays. The purpose of the program was to prevent the chaos, disappointments and hard feelings associated with poorly constructed undergraduate proposals.

Description of Program
The Office of Research & Creative Activities (ORCA) posted the annual ORCA Grant Call for Undergraduate Projects with a notice that release of funding would be contingent on IRB approval. Simultaneously we posted a notice that the IRB would sponsor a series of two-hour workshops to help students complete their IRB proposals. An experienced IRB member volunteered to provide four workshops each week for four consecutive weeks during the ORCA Grant application period. Workshops were scheduled in media labs outfitted with 20+ computers and a projector. Students registered online to attend one of the workshops. Students were instructed to bring a flash drive with their ORCA Grant proposal to enable appropriate cutting and pasting into the IRB template.

Each workshop began with a power-point presentation regarding the history of human subjects protection and the essential IRB processes. Students then logged on to the IRB website and brought up the proposal template. The presenter then walked students through each component of the proposal, answered questions, gave tips, suggested specific language that met IRB requirements (e.g., "minimal risk"), helped structure consent processes and forms, and advised students regarding extra-IRB processes (e.g., school district IRB processes and approvals). Students drafted their IRB proposals during the workshop and were instructed to polish them with their faculty advisors before submitting them to the IRB. Students were directed to other resources outside the university to expedite their approvals (e.g., local school district offices).

In the 2008-2009 ORCA Grant season, 800 undergraduates applied for funding. 313 studies were funded. 200 funded studies required human subjects protection and review by the IRB. Of those 200, less than 5 percent were denied or required extensive revision before final approval. Students, faculty advisors, and IRB members noted how the workshops supported student success. Failures, frustration, disappointments and hard feelings were avoided all around. One faculty member that has only conducted animal research participated in one workshop to prepare his first human subjects proposal. He found it extremely helpful and received approval easily. A new IRB member attended the workshop to enhance her understanding of how to consult with students and faculty to enhance their success.

Refinements for the 2009-2010 funding season include having multiple members of the IRB conduct the workshops. The pilot-program required an extensive time commitment from one IRB member which can't be sustained long-term.
Assessing the Efficacy of Your After Hours Research Answering Service

Author: Tammy J. Capozzoli

Background
Simple listing of investigator and research staff office numbers and hospital operators as a back up is not an effective method of communication for research subjects.

Description of Program
The Research Compliance Office conducts an annual Quality Assurance (QA) Audit of the After Hours Research Answering Service to assess the following: (1) Whether the Research answering service is appropriately handling calls from subjects and (2) Whether investigators have provided adequate contact information to the answering service. In September of 2004 an audit was conducted to assess compliance with the after-hours contact requirements for greater than minimal risk research studies. The primary contact number provided on most consent forms was the VA page operator. The audit staff experienced very limited success in contacting study clinicians through the VA page operator. The results of this QA identified a need for the VAPHS Office of Research to contract with an answering service that will assist research subjects in contacting research study clinical staff after hours.

In February 2005, the VAPHS Research Office contracted with an outside answering service to provide evening and weekend research subject call coverage. Subjects were provided an 800-number; the subject made one phone call and awaited a call back while the answering service proceeded through a call list to contact the investigator and give him or her the subject’s contact information. Listing one afterhours contact number simplified the information given to subjects on the informed consent document. In addition, investigators could be assured confidentiality of their non-business phone numbers. At that time, the VAPHS Human Research Protections Program Executive Committee determined that all greater than minimal risk studies with moderate or high scrutiny must use the answering service as their after-hours contact method.

Following changes in policy, a follow up QA’s are conducted annually. The first QA audit was conducted in May of 2006. Using office numbers and hospital operator information, the Research Compliance Officer (RCO) was able to reach a knowledgeable staff member in 1 out of 2 cases. Utilizing the methods as described in the 2006 QA, the RCO was able to reach a knowledgeable staff member in 10 out of 20 cases. The results of this QA identified the need for the VAPHS to discontinue use with the current answering service and select a new answering service that could better meet the needs of our research subjects and investigators. The QA conducted in 2008 found that the new answering service contracted by the Research Office appears to be working well. As a result of this audit, it was found that the answering service provides the IRB Office with a summary of each call that it receives, including the disposition of each call. No major issues were identified with the answering service.
Assessment of “Speak to A Regulatory Analyst” (STARS) Program at the University of Michigan Medical School IRBs (IRBMED)
Authors: Robin Sedman, MSN, CIP; Jan Hewett, JD

Background
In an on-going effort to improve investigator and study team personnel experiences with human subject research review committees, for example the IRB, the Office of Human Research Compliance Review (OHRCR) in collaboration with the Institute for Social Research (ISR) conducted an on-line survey. Results of the survey noted twenty seven percent (27%) of investigators indicated that either an email, telephone call, or both had not been answered by the IRB. Of that percentage, 42% were also dissatisfied with the IRB review and approval process for their most recent application. Frustration with the staff or reviewer contact experience then led to an overall general feeling of dissatisfaction with the IRB review process. The Survey… also “indicates opportunities for IRBs to build and maintain relationships with its customers (since) IRB staff is viewed as knowledgeable, respectful and approachable and investigators rely on them as information sources.”

Description of Program
In response to the survey results IRBMED leadership proposed pilot implementation of the “Speak to A Regulatory Analyst” (STARS) program. This initiative permitted direct phone conversations with a Senior Associate Regulatory Analyst (SARA) for two – 2 hour periods per week during the IRBMED’s regular business hours. During STARS hours, the SARA is available to advise callers on new or ongoing research projects, planning for future research projects, Federal and State human subject research regulations, and institutional policies and procedures. The primary goal of the STARS program is to provide immediate point of service telephone consultation regarding research and regulatory issues in an effort to combat real, as noted in the survey, or perceived dissatisfaction with the IRB on research projects conducted by Medical School faculty. Investigators and study team personnel may call the IRBMED office on Tuesdays from 10.00 am – 12.00 pm and Wednesdays from 1.00 pm – 3.00 pm. A brief script is prepared for the intake receptionist who then forwards the call to the SARA. All calls fielded during STARS hours are recorded on the issues tracking system (JIRA) and relayed for recordkeeping and follow-up (if required) to the pertinent regulatory team for that caller. Although the standard practice of triaging callers to the regulatory team continued during STARS hours, those callers who were not able to speak to the regulatory staff assigned to their departments (because of unavailability, e.g. on the phone already, in a meeting, or engaged in work which could not be interrupted) were also triaged to STARS staffer. STARS has been promoted internally and externally using web postings and news articles in print media by the Medical School.

Results: The STARS Program was implemented in February 2009 and to date approximately 110 calls have been responded to by the SARA. The STARS content elements (type of caller, e.g. investigator, caller’s department, subject matter, e.g. regulations, new or existing project or institutional policy or procedure) are collected in a report using the JIRA issue tracking system for analysis.
Assuring Regulatory Compliance for Research Tissue Collection in the Operating Room (OR)
Authors: Raymond Hutchinson, MD, MS; Patricia Ward, MPA; Stephen Harrington, BS; Deborah Day Jansen; Margaret Stoe, MT(ASCP)SBB, CQA(ASQ); Jane Thomson, BSN, MPH, CNOR

Background
The typical operating room environment may lend itself to the collection of human tissue for research without appropriate informed consent. Carefully conceived processes are needed to assure that appropriate research consent is obtained. We will describe such a new process, aimed at assuring appropriate consent prior to research tissue collection.

Description of Program
Non-surgical principal investigators often partner with surgeons at their institutions to obtain human tissue for research. Some institutions also have centralized core facilities or programs to facilitate this activity. However, when use of such central cores is not mandatory, ensuring appropriate validation of research patient consent and chain-of-custody documentation can be challenging. At our institution, we are instituting a system of checks and balances to ensure (1) good communication, coordination, and documentation between non-surgical principal investigators and the surgeons who will collect tissue for them; (2) advance validation that appropriate informed consent was obtained from the research patient; (3) use of the peri-operative “time out” to verify a patient’s research tissue donor status via electronic display in the operating room of information captured at scheduling; and (4) appropriate arrangements for tissue collection and preservation, transit to a research destination, and chain-of-custody documentation.

A primary goal of this system is to assure that only the IRB-approved informed consent document (ICD) is used when an ICD is required. Guidance regarding who can obtain research informed consent will now be provided for surgeons and staff in the OR. Detailed information regarding roles in research for operating surgeons will be provided, including responsibilities and limitations for “delegated” surgeons versus surgical co-investigators. Further, the coordinated engagement of OR schedulers, circulating nursing staff, and tissue procurement core staff facilitates timely entry and sharing of information via the electronic system, appropriate handling of research specimens, and accurate tracking of research specimens to appropriate research labs. The process being established will be detailed and early results of system performance reviewed.
Audit Program Extends to the IRB’s electronic Research Compliance Solution
Authors: Benjamin R. Byington; Dawn Lowe-Gooden

Background
Internal institutional research oversight bodies, such as an Institutional Review Board (IRB), should never be exempt from internal monitoring of their practices and procedures. A check & balance system should be in place to ensure that these groups are complying with their own defined mission, institutional policies; as well as, applicable state and federal regulations. Such an evaluation process can also serve as a valuable tool for overall process improvement. One such program was developed to evaluate the electronic compliance solution for the management of human subject’s research protocols implemented for the IRB at Cincinnati Children’s Hospital Medical Center (CCHMC). This program also serves to evaluate the Human Research Protection Program (HRPP) and IRB’s compliance with institutional policies and procedures related to the review and oversight of research involving human subjects.

Description of Program
The CCHMC HRPP Manager and staff noted errors in the management and tracking of IRB-approved informed consent documents (ICDs) within the IRB’s electronic compliance solution, ePAS (ePAS is CCHMC’s application of the Click Commerce Compliance Solution instituted in February 2008). The HRPP Manager requested that a Research Compliance Specialist from the Research Compliance Program of the Office of Research Compliance and Regulatory Affairs (ORCRA) perform an audit of this system to gain a better understanding of the extent and overall impact of the identified issue.

An audit was conducted by comparing the IRB-approval notification dates with the date stamps and version control on ICDs to ensure that there was no conflict between the two. This was completed for every IRB-approved study with an approved consent document. After the audit was completed, a report was generated summarizing all of the findings. It was then forwarded to the ORCRA Director, HRPP Manager and Research Compliance Manager for review and assessment. The report detailed any specific deficiencies identified; whether deficiencies were either administrative or represented potential non-compliance; whether system and/or process changes were needed to prevent future occurrences and what resources would be needed to correct any current deficiencies. A corrective action plan was developed to correct all deficiencies, including appropriate notifications and follow-up regarding any deficiencies that represented potential non-compliance.

Suggestions for Future Uses: As a result of this process, the need was identified for the development of a new aspect of the CCHMC Office of Research Compliance and Regulatory Affairs’ (ORCRA) Research Compliance Program’s current activities related to the oversight of research involving human subjects. This component will likely include a routine IRB focused review of a randomly selected component or components (initial submission, meeting minutes, problem reporting and review, continuing review, etc.) of the review/approval process of the IRB and HRPP to assess compliance with CCHMC policy and procedure as well as applicable regulations. This additional function would complement the current function of project specific review of IRB records and documentation that occurs in conjunction with the Research Compliance Program’s review of investigator compliance.

Suggestions for Implementation at Other Sites: This program allows for process evaluation and improvement, which can improve compliance with institutional, state, and federal regulations; as well as, overall resource allocation.
Beyond Subject Injury: Development and Implementation of a Comprehensive Clinical Research Risk Program

Authors: Carroll Child, RN, MSc, CCRP; Bruce G. Flynn, MS

Background
While major research institutions, under the Federal regulations, state laws, and accreditation requirements, constitute Institutional Review Boards (IRBs) that are charged with responsibility for analysis and mitigation of research risks to subjects, there is an absence of a corresponding set of external regulation to drive risk assessment and mitigation for other, non-subject-injury related risks which may affect the individuals involved in clinical research (investigators, their staff, IRB Chairs and members, and administrators) as well as the sponsoring institution as a whole.

Description of Program
Goals/Aims: To develop, in partnership with the University of California, San Francisco’s (UCSF) Human Research Protection Program (HRPP), Risk Management, Office of Legal Affairs, Office of Sponsored Research and the major research institutes, schools, and divisions, a broad-based Clinical Research Risk Management program that utilizes risk management trending and root cause analysis methodologies to identify, prevent and/or reduce a range of research-related risks encompassing but not limited to subject injury, affecting the entire clinical research enterprise at UCSF.

Description Of Program:
Phase I: Development of Subject Injury Program Since its initial development in December, 2005, the Clinical Research Risk Management (CRRM) program at UCSF has focused on: 1) Incident-based response processes to insure maximum timeliness in the reporting, evaluation, and payment of claims for subject injury; 2) Refinement and application of University of California’s systemwide Subject Injury Policy.

Phase II: Development of a Comprehensive Research Risk Management Program In collaboration with the HRPP, the CRRM will expand its management of subject injury risks to encompass assessment of a broader array of clinical research-related activities, procedures, and structures at UCSF in order to identify those aspects of clinical research that pose potential risks to non-subject participants, and to the overall financial, operational, and reputational interests of the institution.

Discussion: Having constructed a functional and institutionally-integrated framework for the analysis and management of subject injury events, the opportunity now exists to significantly strengthen the effectiveness of our research risk program by expanding the scope of risk management activities (primarily through education and training on risk prevention/reduction/mitigation) to include all key individuals engaged in the clinical research enterprise at UCSF. An evaluation component of the program will allow for assessing both the utility and cost of the Phase II expansion and its applicability to other HRPP and research risk management programs.
Biobanking Considerations & The C-PROBE Paradigm
Authors: Crystal Gadegbeku, MD; June Insco, BA, CIP

Background
Biobanks promise important advances in understanding disease and developing new treatments. They facilitate translational research by collecting data and specimens and making them available to investigators. Yet, despite biobanks’ increasing numbers investigators and IRBs possess few tools to assist them in developing and reviewing these facilities.

Description of Program
Clinical Phenotyping Resource and Biobank (C-PROBE) Core is a research core within the NIH-sponsored P30 George M. O'Brien Renal Center. We call C-PROBE a complex biobank, because it not only includes on-going data collection and subject interactions, but also releases its data and specimens according to policies designed to assure that their uses offer maximum benefit to the biobank. A simple biobank one houses a single collection and imposes limited restrictions on the release of data and specimens.

C-PROBE's primary objective is to develop an infrastructure enabling communication among patients in clinical care settings throughout southeastern Michigan and Chicago, as well as biomedical investigators conducting translational research in kidney disease. C-PROBE collects data blood, urine, and kidney tissue. Specimens and/or names of those patients interested in participating in future studies are released to investigators only after C-PROBE has conducted scientific review of proposed protocols. In its early stages, C-PROBE consulted with the IRB. We found applying considerations in the regulations and in the literature on biobanking to be difficult and cumbersome.

Using C-PROBE as a model, we have created checklists with supporting documentation that will serve all biobanks, from the simple to the complex. Unlike traditional protocols designed to test hypotheses, these checklists address the peculiarities of biobanking protocols.

Some considerations included in the checklists:
- Storage-security, disaster plans (such as major power outages),
- Personnel,
- Privacy and confidentiality,
- Informed consent.

Content of supporting documentation:
- References to published articles,
- Regulations, accompanied by a brief overview of their implications,
- Resources to consider (such as data storage programs with robust security).

Program Evaluation: We circulated draft checklists to experts within the University of Michigan and the University of Michigan Medical School. Various investigators, IRB members and staff, and ethics committees reviewed the lists, and then recommended additional considerations for inclusion and offered comments regarding accuracy and clarity. Initial feedback has been positive. We revised the drafts and posted the final checklists on the IRB website.

Implementation and Suggestions: We will use these tools in consultation with investigators as they develop future bio/databanks and use materials from them. We recommend other institutions be proactive in development of similar tools. Any of our web-postings may be used by other institutions provided the University of Michigan is credited. We recognize that the checklists are in an early phase of development. In the coming years we will continue to assess their effectiveness and to modify them as necessary.
Blogging at the IRB
Authors: Rebecca Abel, MA; Tony Medure, MA, CIP, RAC

Background
In an effort to stay current with changing media trends, the Vanderbilt IRB has started blogging to communicate pertinent information to the research community. Blogging has become an increasingly popular method of communication on the internet. According to technorati.com’s “State of the Blogosphere”, eMarketer reported 22.6 million US bloggers with 94.1 million US blog readers (50% of internet users) in 2007. Trends in research, changes with local policy and procedure, and helpful hints for principal investigators can be communicated effectively through the IRB Blog. In order to increase readership, we examined the best methods to advertise the IRB Blog. This program evaluated the number of visitors to the IRB blog and the increase of site traffic over time using built-in tracking software on WordPress. In addition, we evaluated the effectiveness of advertising the IRB Blog at Vanderbilt using an online survey validated through Vanderbilt’s in-house data capture and survey service, REDCap.

Description of Program
The Vanderbilt IRB News blog (http://irbtipoftheweek.wordpress.com/) was created to be an efficient way to present timely information to the research community. This medium has immense potential for delivering valuable information to investigators, but it is limited by how often our researchers view it. Our first objective was to utilize a tool to measure the blog’s current web traffic. With this baseline established, we could then focus our attention to increasing the blog’s readership through targeted advertisements using several different mediums in a phased approach with the overall goal of increasing the research community’s awareness of the blog. A protocol analyst and a regulatory affairs and compliance specialist collaborated on this project in an attempt to measure the effectiveness of various advertising methods to increase research community awareness of the IRB Blog.

The program was evaluated first by installing SiteMeter monitoring software on the blog. Site visits were recorded two weeks after installing the software to establish a baseline. From this point, we implemented a new advertisement form (flyer to departments, broadcast email, notice on the IRB webpage) every two weeks for 10 weeks. At the end of each two week period, the number of site visits were evaluated to determine the effectiveness of our advertisements. A survey was administered at the end of the research period to obtain visitor feedback and evaluate program efficacy. There is undoubtedly a balance to be struck between advertisements that encourage people to use the blog and over saturation. Knowing the most effective forms of advertisements increases the likelihood of contacting and drawing our target audience.

Through this evaluation process our Blog will more likely realize its educational potential in the research community. Other Institutional Review Boards may find that implementing a blog helps educate the research community in a more readily available and accessible media outlet. Increased understanding of IRB policies, procedures, and OHRP guidelines will aid in researcher understanding of human subjects protections.
Building Bridges Between Community Advisory Boards and Ethics Committee
Authors: Rosemary Musesengwa, BSc, MPH; Rutendo Gutsire, BSc, MPH, MSc

Background
The NEC (National Ethics Committee) in Zimbabwe has a sufficient Human Research Protection System (HRPS) that is unknown to the communities it protects. This protection system is arguably paternalistic and in the past there have been haphazard efforts for the NEC to firmly connect with the research communities. Community participation through CABs in research has been argued to be an effective method of protecting researched communities. In order to strengthen the HRPS, the NEC embarked on a public awareness programme of the role of research gatekeepers (IRBs, CABs) and how they can network for the benefit of the participants they protect.

Intended Outcomes:
- To create a gateway of information and a forum where CABs meet the NEC and share ideas on how to best protect participants
- To explore ways in which the CAB could form part of the Human Research Protection System

Description of Program
There are five components to the program as follows:

A. Participation in Research Forums. In the 2008 Annual Health Research Forum the NEC adopted the theme “Empowering Communities through Research” and dedicated the whole forum to community issues.
B. Monthly CAB/NEC meetings. This is the forum where CAB and representatives of the NEC share ideas and find means and ways of solving problems without the researchers.
C. Annual CAB meeting. The NEC dedicated funds to sponsor CAB members from different studies and communities to meet and network annually.
D. CAB Training series ie Research Literacy, Research Ethics. This two day training covers ethics and research literacy and how to review protocol.
E. Development of CAB newsletters, pamphlets, and CAB Handbook. This material is targeted for dissemination to research participants.

Evaluation: As the NEC and CAB get acquainted information sharing has been enhanced. The CAB is managing to articulate their views on various ethical issues. They now may influence decisions on how the consent process is done. They also started a process of passing on participant complaints to the NEC. Their participation in Forums has led to the NEC appreciating the major role of the CAB. The NEC is exploring ways in which they can be part of the HRPS without creating another bureaucratic hurdle. This enhances ownership of approved studies by CABs.

Suggestions: Other IRBs can use this approach as it gives you an insight of exactly what happens in the community compared to the IRBs own prejudiced paternalistic judgment of what is good and bad for the participants. A strong link with the projects is also vital for this process to flow to avoid duplication of efforts.
Challenges of a Faith Based IRB
Authors: Gary Parker, PhD, MS, BSN; Tracy Higgs, MS, CNS, RN; Trish Quarles; Linda Fanning, MS, BSN

Background
The advances in healthcare that have occurred over the last decade have drastically changed the way medicine is being practiced. Many of the advancements are due in part to clinical research being conducted at private and public healthcare institutions throughout the United States. While most of these trials are governed by IRBs that must adhere to strict federal and state guidelines in addition to the rules and regulations of the protocol, there are other IRBs that must also answer to the ethical standards of the Catholic doctrine. For these Catholic faith based institution IRBs, consideration must not only be given to the state and federal guidelines, but also how the Catholic Church’s position may impact their decision when reviewing potential research trials.

This poster will educate the reader by sharing the challenges that many Catholic institution IRBs face on a daily basis. It will also discuss how members must put their own beliefs and morals aside to allow the Catholic doctrine to guide their decision making. This poster will describe how controversial issues such as contraception, end of life care, tissue transplantation, gene therapy, Reiki and alternative therapies are addressed and resolved so that research may continue within the community.
Challenges of Securing Privacy and Confidentiality in Behavioral Research in Post-Conflict Liberia
Authors: Fred Sosu; Jemee K.Tegli, BA; Stephen B. Kennedy, MD, MPH; Mawen Gobeh, BBA; Curtis H. Taylor, BSc; Cecelia Morris, MSN; Matthew Warlonfa

Background
The issue of privacy and confidence can be meandering as most participants may not or are not aware of the consequences. It is questionable whether researchers from developed countries are well prepared for the enormous responsibility of respect and trust placed upon them. Therefore the intention of privacy and confidentiality is for the purpose of letting participants know that information gathered from them is sole for the purpose of the research outcome and not otherwise. Privacy and confidentiality are vital in human research study as important information is accrued as a result of the findings. In situations where the data are collected like in the case of Liberia, researchers took several steps to ensure the confidentiality of their participants’ information, including:

- Use participant codes to label data instead of using names, and keeping a separate list of code-to-name match-ups.
- In interview studies, use the participant’s first name only (or even using an alias) when recording or publishing data. Most of the time, an alias will suffice, and is especially important to protect the participant if the published data includes other identifiers such as age, gender, community affiliations, or place of residence.
- Be careful not to publish enough information that the participant can be identified.

Description of Program
In Liberia receiving IRB approval for the conduct of behavioral or evidence-based research is an imperative. This is done through the recruitment process where assent and or informed consent are obtained from participant and parents for inclusion into the study. It is important for researchers to understand how to conduct their research in a manner that honors this trust, both for the sake of their research participants and for the sake of their study’s validity. Even the most well-intentioned and well-trained researchers can make mistakes in this area, so it is essential to think carefully about how to ensure that participants submits informed consent to participate in a research study. As is been done at my institution, the issue of privacy and confidentiality is at the crux of our work. Strictly adhering to ethical values is what we do in Liberia when dealing with subjects enrolled in our studies.

Additional Information
Confidentiality is equally important and refers to information about the person that has been revealed to the researcher. Especially in medical or behavioral research, researchers are in a position of responsibility and dealing with a great deal of very personal information that their participants have agreed to disclose. In Liberia, safeguarding this information is a key part of the relationship of trust and respect that exists between the researcher and the participant. The Institutional Review Board is also observant in the process of the research study as a balancing factor. Depending on the type of study, personal identifiers such as names, birthdates, places of residence etc. may or may not have to be collected.
Clinical Trials Network Cooperative Approach to Implementing Exception From Informed Consent (EFIC) for Emergency Research
Authors: Deneil Kolk; Phebe Brenne; Robert Silbergleit (on behalf of the NETT investigators)

Background
The Neurological Emergencies Treatment Trials (NETT) network was created by the NINDS to perform clinical trials of very early interventions in patients with acute neurological problems like seizures, stroke or neurotrauma. Because such patients are often comatose and the treatments being studied are given immediately in the ambulance or ER, trials in the NETT often require exception from informed consent for emergency research (EFIC) as described at 21CFR50.24. Implementing these frequently unfamiliar regulations within a network of 17 academic Hubs and many more community hospital Spokes is challenging. To optimize the protection of human subjects, enhance compliance, and improve efficiency the NETT developed a cooperative approach to EFIC and community consultation (CC).

Description of Program
The NETT approach to EFIC promotes collegiality and collaboration within and between clinical sites, and provides centralized resources and coordination while respecting local control. The NETT Human Subjects Protection Coordinator, a full time clinical research professional, is a central contact who facilitates EFIC, and leverages the collective experience of the network to address individual site issues as they arise. NETT also organized a national conference to bring investigators and IRB leaders from each Hub together for a day of education and discussion. This meeting familiarized participants with the EFIC regulation, allowed Hubs without EFIC experiences to ask questions, and allowed those with EFIC experience to share their solutions. Local IRBs/investigators always determine the optimal strategy for each site, but NETT provides EFIC resources including educational videos, surveys, and advertising templates, sample IRB applications, menus of CC suggestions, and a web-based repository of site developed materials for sharing between Hubs. Electronic summary forms standardize reporting, aggregating, and sharing information collected during CC activities between sites, IRB’s, and regulators.

Currently, 14 Hubs have reported 164 CC activities involving >30,000 participants. Feedback from 5,126 individuals included 41,096 closed-ended and 1933 open-ended responses. Qualitative coding of responses expressing support or concern for EFIC and the proposed trial is ongoing, but 75% of closed ended answers and 69% of open ended comments are supportive. The most common CC activities are visits to existing group meetings (39%) and focus groups/interviews (19%).

NETT’s second trial requiring EFIC has recently been funded and approved. The current cooperative approach to EFIC implementation within the NETT will be continued and enhanced as our experience accumulates. NETT provides an unprecedented opportunity to explore EFIC implementation and help identify best practices that may be useful to others beyond the network.
Columbia University IRB's Education and Training Initiatives: Bridging The Road to Success
Authors: Heather Butts, JD, MPH, CIP; Susie Kim, CIP; Malini Lall; Jessica Randall, CIP; Brenda Ruotolo, CIP; Alavy Sos, CIP

Background
An effective HRPP requires that individuals from all components be knowledgeable in regards to their particular role and the basic regulatory framework. The Columbia research enterprise is extensive in size and broad in scope and nature of activities, including biomedical, behavioral, and epidemiological research, as well as studies in the area of health services. Five IRBs review nearly 8000 submissions each year. Effectively educating all involved parties requires resources, creativity, and collaboration.

Description of Program
The Education and Training Committee, one of several standing committees established in 2003 within the IRB office, holds regular educational sessions for IRB staff, members of the Columbia research community, and IRB members, in addition to a community outreach component. Committee membership is comprised of IRB staff, each of whom contributes to an active, year-round schedule of events, including monthly IRB-investigator meetings, an annual IRB conference, “IRB 101” sessions for researchers, electronic submission system training for IRB members, orientation for new members, staff training sessions on various topics, and interaction with community representatives to enhance the public understanding of research participation. Staff have presented or attended more than 350 events. Four subcommittees, based on target audiences, have been established to efficiently manage initiatives, which originate at the subcommittee level before being confirmed by the Committee. Ideas for topics may develop from QA activities (e.g., evaluation of reasons for protocol returns), faculty feedback about forms, guidance, or processes, community interaction (e.g., attendance at community board meetings), IRB members (e.g., request for guidance about a challenging review), and staff members’ observations.

Evaluation Method:
Effectiveness of initiatives is evaluated in various ways, appropriate to audience and activity. The Research Personnel subcommittee distributes evaluation forms at each session and works with the University’s Center for Education Research to effectively interpret and utilize the responses. Improved quality of submissions is evidence that outreach efforts are effective. IRB managers provide feedback about the responses of IRB members to educational efforts, which has led to refinement of the handouts and presentations. Staff members are encouraged to comment on topics and format of staff training sessions and to provide suggestions. Community leaders, faculty who work with area residents, and IRB lay members are important conduits for feedback about outreach efforts.

Additional Information
Depending upon resources (staff, funding, time) available, this program can be adapted in some form to many institutions. At Columbia, we are continually refining format and topics based on feedback from audiences, QA activities, and staff suggestions.
Constructing an Automated Online IRB Application: A Collaborative Process
Authors: Dennis D. Kerkman; Douglas Burns; Dawit Wubshet; Kevin Payne; Amber Dailey-Herbert; Wen Jung Hsin; Lisa Bunkowski; Denise Lowe; Michael Eskey; Ann Schultis

Background
Park’s unique nature as the second largest online program in the country with 42 campus centers nationwide presents unusual challenges for research ethics oversight. In order to create an inclusive approach for IRB application review and approval, we created and instituted a fully online IRB application process.

Description of Program
The new approach has expedited processing and offers an inclusive representation of faculty (traditional, distance, and online) in the review process and ability to access resources. The Park IRB committee includes 10 annually elected representatives from each college, including two faculty from distant campus centers, an ex officio university attorney, and a non-affiliated local community representative. Members complete annual training in the use of the IRB online application website and the ethical obligations of faculty and administrators in research oversight. All prospective investigators complete the NIH Protecting Human Subject Research Participants certification program. As a supplement to the online system, we have created a dedicated website educating faculty and students on IRB definitions of "research," the three legal categories of application review (exempt, expedited, full board review), the type of informed assent and consent letters needed for different types of research (e.g., focus groups, surveys, experiments), and an overview of our program (via a video of the annual IRB educational presentation). The initial page of the online application presents a list of standard qualifying questions regarding the protected status of participants, whether the research involves sensitive topics, or involves external funding. The system then automatically determines from the investigator’s initial answers whether the proposed project is classified as "exempt", "expedited", or "Full Board Review." Supporting documentation (such as participant descriptions; recruitment; letters of informed consent/assent; methods; data collection instruments, protocols and procedures; and debriefing procedures) are attached directly to the application. For "exempt" and "expedited" applications, a reviewer is assigned randomly and anonymously. When a majority of members have voted for or against approval, the investigator is automatically notified via email and the decision is logged into the secure section of the website accessed only by IRB members. Applications are password protected and can be saved and edited by the applicant until submitted for review, and again in the event that the application is not approved. Last year, this system processed more than 80 applications with an average turnaround time of less than one week. This process exemplifies a dynamic, self-correcting, collaborative effort.
Cost Benefits of an Institutionally-Based Subject Injury Compensation Program
Authors: Carroll Child, RN, MSc, CCRP; Bruce G. Flynn, MS

Background
In the absence of federal or other national regulatory requirements mandating the provision of compensation to subjects injured during their participation in research, work by Steinbrook (NEJM, 2006) and others has found that only a small minority of the academic medical centers surveyed had policies that for the provision of free care or treatment for study-related injury. At the same time, there is little information about the cost effectiveness of responding to subject injury (SI) cases and claims through a treatment program.

Description of Program
Goals/Aims: To measure the total number of subject injury cases incurring payment costs to the UCSF SI program and the cost differences between SI claims that were litigated versus not.

Methods: In 2005 the University of California, San Francisco (UCSF) established a campus-based Subject Injury (SI) Program to more fully apply and refine the existing University of California systemwide Subject Injury Policy. Working in partnership with key campus entities (the HRPP, Office of Legal Affairs, Sponsored Projects and Risk Management) and the University of California Office of the President, UCSF’s campus-level SI program initially assesses and manages all subject injury claims arising from UCSF-affiliated clinical research. During the first quarter of 2009, the UCSF SI program conducted a retrospective review and analysis of all SI claims filed with the UCSF Subject Injury program between January 2006 and December 2008.

Results: Of all claims filed (12), half (6) incurred payment costs. Of the claims incurring costs, half (3) were litigated (or in litigation) outside of the SI program and the remaining half were managed and settled within the SI program. The payment costs for the litigated claims were, on average ten-times greater than those for non-litigated claims. All other claims (6) were found to have either no injury requiring treatment, were covered by alternate payer (insurance, industry sponsor) or the injuries were determined to be unrelated to research and therefore incurred no costs to the SI Program.

Discussion: Our review of subject injury claims across a two year period suggest that large direct cost benefits may result when subject injury claims are managed and settled within an institutionally-based SI treatment compensation program as opposed to settled through litigation and that a significant number of SI claims (50%) can be resolved without sustaining any payment costs to the program.
Creation of a Comprehensive Research Patient Data Warehouse at Washington University
Authors: Rakesh Nagarajan; Thomas Holdener; Bradley Evanoff; Thomas Bailey; Mark Watson; Kenneth Polonsky

Background
Major goals of biomedical research include the translation of novel advances in science to improvements in patient care, relaying findings from clinical studies back to the bench for further refinement of our understanding of the disease process, and the dissemination in medical practice of findings from clinical studies. To realize these goals, researchers must be able to integrate complex biomedical data sets that include health record information with the results of molecular profiling and genome annotation information and must also have access to clinical data on large numbers of patients. Most researchers do not currently have ready access to patient data for the purposes of review preparatory to research, retrospective data mining projects, and participant identification. While data on individual patients may be acquired and recorded manually by viewing such individuals’ health records, such data collection by individual chart review is not feasible for many studies. Furthermore, this activity currently poses significant privacy and confidentiality risks to participants. More seamless but regulated electronic access to patient data would not only broaden the scope of the research data available, thereby improving the integrity and generalization of the research conclusions, but would also minimize the privacy and confidentiality risks to individual subjects by restricting data access to elements directly relevant to a given project.

Description of Program
At Washington University, we are developing a patient database called the Clinical Investigation Data Exploration Repository (CIDER). CIDER will enable clinical research that is currently difficult or impossible to perform and will simultaneously allow greater oversight and security for access to patient data. CIDER will contain comprehensive medical record information from 1993 forward and will maintain this data in identified fashion. However, strict and sophisticated security through a web-based interface will enable investigators to access this information as anonymized, de-identified, limited, or identified data sets based on each study's review and human studies approval. To establish CIDER, we submitted a protocol for review and approval to our Human Research Protection Office. We propose to discuss several significant ethical, regulatory, and social issues that were encountered during this review including the following:

- Does the creation of a database from health records constitute human research?
- How should investigators’ use of CIDER be monitored in order to maintain regulatory compliance while facilitating ethical research?
- Under what circumstances should informed consent be required before medical record data are entered into such a clinical data repository?
Critical Strategies in Research Compliance: Managing the Research Complaint
Authors: Nancy M. Pultorak; Alyson M. Hettenbach; Ann N. Sieber; Gregg Fromell

Background
One of the keystones of a vital human research protections program is a coordinated and timely response to a spontaneous research complaint. Research complaints may originate from various sources including, research subjects or their families; clinical research coordinators or study staff; investigators and faculty; institutional offices; government agencies; industry sponsors, and contract research organizations. This abstract describes a uniform approach to receiving, communicating, managing and documenting findings from research complaints reported to the Office of Human Research (OHR) at the University Of Pennsylvania School Of Medicine.

Description of the Program
Research complaints reported to OHR are processed by a Research Compliance Team (RCT) auditor who completes a standardized intake form. Complaints originating from research subjects are immediately forwarded to the Office of Regulatory Affairs (ORA) for further processing and management. ORA may request an OHR audit investigation of a research subject complaint. Other research complaints are assessed by the OHR Director for institutional triage and assigned to an RCT auditor. Details of the complaint are shared with the Principal Investigator without a breach of complainant confidentiality. The RCT auditor follows the OHR central auditing program standards, including regular communication with the Principal Investigator and his/her staff as appropriate. Modification of the audit scope occurs at the discretion of OHR RCT Director.

Findings
Findings from the investigation are categorized as unfounded, or confirmed, in part or whole. If confirmed, a formal management plan is created to document auditing findings and the corrective action plan. This written document is provided to the Principal Investigator during a face to face debriefing meeting. Findings specifically related to human subjects protections are immediately reported to the ORA by the OHR. In addition, the ORA receives a copy of the management plan Audit findings are captured in the restricted OHR compliance database, and hard copy documents are retained in a confidential file.

Program Evaluation
Formal processes for managing research complaints fosters standardized management and clear communication with PIs, research staff, and institutional officials leading to enhanced responsiveness to research complainants.
Crucial Choices: A Pilot Study of Interactive Research Ethics Education Methods for IRB Members at the University of Pennsylvania’s Office of Regulatory Affairs
Authors: David Perlman, PhD; Megan Kasimatis Singleton, JD; Tracy Ziolek, MS

Background
IRBs encounter a host of regulatory and ethical issues for which advanced training is both appropriate and necessary. Most advanced IRB member training is done internally, on an ad hoc and informal basis, with few standards regarding content, substance, format, or evaluation. This project represents an initial attempt to subject one education solution to feasibility pilot testing to overcome these educational challenges.

Description of Program
The Office of Regulatory Affairs at the University of Pennsylvania (Penn), which operates 8 IRBs, has partnered with E4 – Eclipse Ethics Education Enterprises, LLC (E4) to subject E4’s educational technology, called Crucial Choices, to feasibility testing with Penn’s IRB. Crucial Choices ethics scenarios use open-ended choice opportunities for learners to direct their own path through an ethics scenario, see the ethical consequences of their choices, and use critical thinking skills to make ethical choices. Crucial Choices is designed for both live and online delivery and represents a multi-modal method of learning by simultaneously targeting all four major adult learning styles. We will present the results of our proposed feasibility test of this educational intervention.

The educational intervention will be:
§ Short in duration such that it could be built into a busy IRB meeting with a large agenda
§ Focused in substance such that it can be done in a short amount of time and add to the fund of knowledge of issues frequently encountered by IRB members
§ Built using interactive technologies such as an audience response system for remote polling and use of critical thinking skills
§ Part of a large library of short, focused modules so that the education can be delivered live and represent evolving trends in human research protection topics
§ Recorded or podcasted so that it will be available as refresher training

This poster will present our findings about this pilot project, including an evaluation of the training intervention and suggested improvements. E4 will use the results of the test to further develop and refine its Crucial Choices offerings.

Additional Information
Crucial Choices is a trademark and copyright of E4. Disclosure: David Perlman, Ph.D., the inventor of Crucial ChoicesTM and the President & Founder of E4, is also a part-time, adjunct senior lecturer at the University of Pennsylvania School of Nursing.
Data Sharing & Security Framework: An Ethical, Regulatory & Proprietary Analytical Tool
Authors: Julie Wietzke, MHSA, MLS; Elaine Brock, MHSA, JD; Rachel Nosowsky, Esq; Alex Kanous, JD, MSI

Background
The recent explosion in volume of biomedical research data and the dispersion of expertise and knowledge best suited for realizing the scientific and public health benefits harbored within these data sets makes the sharing amongst collaborators of these data of particular importance. In addition, conditions requiring data sharing plans, such as those placed on NIH grants exceeding $500,000, further incentivize the development of data sharing systems. However, the construction of such systems manifests myriad hurdles, including not only the technological mechanism by which the data will actually be shared, but also the ethical, regulatory, and proprietary concerns that stem from data sharing.

Description of Program
The Cancer Biomedical Informatics Grid (caBIG) initiative is a project initiated by the National Cancer Institute’s Center for Biomedical Informatics and Information Technology (NCI-CBIIT) that seeks to overcome these hurdles. Its mission is to create an information network that facilitates the sharing of data amongst the community of cancer researchers, thereby simplifying collaboration and accelerating research cost-effectively.

In achieving this end, the project is guided by four principles: Open Access, Open Development, Open Source, and Federation. While initially focused on cancer research, the technologies and tools developed under caBIG will be applicable to wide ranging therapeutic and research activities. The basic tool for data sharing within caBIG is the Data Sharing and Security Framework (DSSF), developed within the Data Sharing & Intellectual Capital Workspace. The DSSF functions as a decision support tool that assists organizations interested in data sharing via caBIG in determining which data can be shared and the necessary access and data security controls. It does this by defining four elements under which the organization must assess the sensitivity of the data to be shared: Economic/Proprietary/IP Value; Privacy/Confidentiality/Security Considerations; IRB or Institutional Restrictions; and Sponsor Restrictions. This assessment results in an overall determination of the sensitivity of the data to be shared, and the assignment by the organization of a low, medium, or high sensitivity data rating drives the selection of the access controls placed on that data. Resulting mechanisms range from unrestricted general access, through limited access defined by standardized terms, to access restricted to only those who have engaged in individually negotiated bilateral or multilateral agreements. However, as the DSSF is only a guideline, the specific agreement the organization decides upon will be based upon and reflective of its particular needs.
Decentralized Exemption Determination Process

Authors: Caroline Miner; Francine Jones; Erin Loos

Background
Office of Human Research Protection guidance has long held that investigators should not determine whether their own research is exempt from the Common Rule and IRB review; however, the regulations do not specifically identify who has the authority to make these determinations. The result is that many institutions designate the IRB as the decision authority. The first author participated on the Social and Behavioral Sciences working group originally of the National Human Research Protections Advisory Committee (NHRPAC) and then later funded through NIH’s Office of Behavioral and Social Sciences (OBSSR). In the paper, “Institutional Arrangements for Reviewing Exempt, Expedited, or Other Research and Research-Related Activities,” the working group noted a number of problems with centralizing exemption determination authority at the IRB, including increased burden on the IRB and lack of timeliness in the reviews. This poster describes our implementation of the working groups’ recommendations and the impact of program implementation on timeliness and accuracy of reviews.

Description of Program
The OUSD(P&R) has authority over a medical school, K-12 school system, managed health care system, the Defense wide personnel system, and other institutions. Other than research at the medical school, the majority of the research is noninvasive social science research. Much of the research falls in the gray area between research and “other” where determination of applicability of the Common Rule is a judgment call. Each institution designates an individual to serve as the Exemption Determination Official (EDO). The individuals must be endorsed by the regulatory oversight office and the institution. A dual reporting structure prevents the EDOs from being too conservative or too liberal in exercising their authority. EDOs receive direct training from the oversight office and “on-the-job” training. Until they are qualified, all of their determinations must be approved by the oversight office. Once they complete training and make independent determinations, their files are subject to review by the oversight office. Efficiency of the program is measured by processing time for submissions and determinations as measured by EDO reviewer files and self reports. The effectiveness of the program is measured in correctness of the EDO determinations as measured by review outcomes of our program audits.

Results:
For established EDOs, most exemption or not human subject research (NHSR) determinations are made within 48 hours of receipt of the proper documentation. At this time, we have conducted at least one oversight review of our institutions with fully qualified EDOs, and we have not found any significant review errors. This program provides an oversight that not only set standards across the institutions for human subject protections, but also higher consistency in research reviews, open communication between Headquarters Office and local institutions, and remarkably efficient reviews that are based in the research environment.

Additional Information
The first author participated on the Social and Behavioral Sciences working group originally of the National Human Research Protections Advisory Committee (NHRPAC) and then later funded through NIH’s Office of Behavioral and Social Sciences (OBSSR). In the paper, “Institutional Arrangements for Reviewing Exempt, Expedited, or Other Research and Research-Related Activities,” the working group noted a number of problems with centralizing exemption determination authority at the IRB, including increased burden on the IRB and lack of timeliness in the reviews. This poster describes our implementation of the working groups’ recommendations and the impact of program implementation on timeliness and accuracy of reviews. The Social and Behavioral Sciences working groups’ recommendations are posted at

Department Focused IRB Model
Authors: Donna Hoagland; Carlotta Rodriguez

Background
At our institution, prior to 2008, IRB office procedures for processing submissions was based upon an agenda focused model. This model required staff to process submissions based on the submission type; i.e., new application, continuing review request, modification request, adverse event, etc. For example, one management assistant was responsible for processing all new applications, and another for processing only continuing reviews. Because each staff member was responsible for specific data entry related to the submission type, investigators and study personnel were often transferred to more than one staff member for clarification or status regarding their submissions. This was sometimes necessary because a staff member did not have access to the particular information or wasn’t familiar with the issue. At other times this was unnecessary. Although staff could have assisted the investigator with his/her second question by checking status in the database, etc., instead, they would indicate that another staff member was responsible for that type of submission and transfer the caller rather than assist them.

Description of Program
On October 1, 2008, we transitioned to a new department focused model. The intended outcome was to improve customer service and have greater accountability of IRB staff by requiring them to take ownership. With the new model, IRB Program Assistants are assigned as liaisons to specific departments within the University. The role of the liaison is to process and coordinate all submissions, questions, prereviews, etc. for a specific department(s) and to assist the IRB Director with educational activities for that department. The new model allows an investigator or research staff member from a particular department to have all of their questions addressed by one staff member rather than be transferred from person to person within the IRB office.

Initially we received very positive verbal feedback from investigators, research personnel and IRB staff. The positive response led us to design an anonymous survey to provide more measurable results. We would like to share the results of the survey at the annual PRIM & R Conference.
Developing an IRB Educational Curriculum

Authors: Dorothy M. Loth, MA; Steven P. Schmidt, PhD

Background
Each summer Summa Health System accepts approximately 25 students for a summer research fellowship. These students are characteristically undergraduates, medical students, and graduate students who typically work on IRB approved research projects during the summer fellowship. The challenge for the IRB is to ensure that the students, many of whom are assuming human subject research duties for which they have no previous training, have an understanding of research ethics, the IRB’s intent and process, and HIPAA. To address that challenge, Summa Health System’s IRB staff have developed a curriculum to educate these summer research fellows that we expect will result in research that is conducted more strictly within federal regulation guidelines and, ultimately, more scientifically sound.

Description of Program
This educational curriculum is designed to provide a certificate course in research ethics and an in depth look at IRB and HIPAA fundamentals. The curriculum begins with a requirement that each summer fellow complete a course from the Collaborative Institutional Training Initiative (CITI). The CITI Program is an online service providing research ethics education to members of the research community. They then attend an orientation in the Department of Research Administration which includes presentations by IRB staff as well as research administration directors, medical library staff, IT staff, and a representative from Human Resources. It is at this orientation that the IRB staff cover fundamentals of the IRB’s composition, role and process, history of medical research ethics, and elements of HIPAA. Many of these students return to continue work at Summa Health System as future summer fellows or in more permanent positions. We expect that training on human subject protection, the IRB’s intent and process and the elements of HIPAA will help to ensure that our future workforce is well educated on proper research practices.

To evaluate the effectiveness of the curriculum the participants completed an anonymous survey as the summer research fellowship program ended. This feedback will be used to refine and expand the IRB’s educational curriculum for future use. Based on the results of the anonymous survey and our personal experience with the curriculum, it will be refined and expanded for use with future summer fellowship participants. At Summa Health System and other research institutions this curriculum has the potential for educating and orienting future summer research fellows and other temporary personnel.
Development and Implementation of an Evidence-Based, Institution-Wide Clinical Research Risk Management Program

Authors: Carroll Child, RN, MSc, CCRP; Co-author: Bruce G. Flynn, MS

Background

Objectives: To develop, in partnership with the UCSF Human Research Protection Program (HRPP), Medical Risk Management, Office of Legal Affairs, Office of Sponsored Research and the major research institutes, schools, and divisions, proactive data-based systems for clinical research oversight to help foster an institutional-wide commitment to preventing or reducing human subject risks at UCSF.

Description of Program

Methods: Since its initial development in December, 2005, the Clinical Research Risk Management (CRRM) program has focused on:

- Incident-based response processes to insure maximum timeliness in the reporting, evaluation, and payment of claims for subject injury;
- 2) Clear descriptions of the roles and responsibilities of key individuals across the institution involved in responding subject injury claims; and
- 3) Refinement of the University’s Subject Injury Policy related to coverage for claims of injury at UCSF.

From this base, in April, 2008, the CRRM program began its next phase of development with the launching of new campus-wide initiatives to proactively facilitate investigator and key university personnel awareness of research safety risks and requirements for investigators and others involved in the clinical research enterprise at UCSF. Moving forward, the CRRM program is applying risk analysis methodology to:

1) Identify the areas of clinical research that pose potential harm to participants’ safety and welfare;
2) Employ incident(case)-based root cause analysis process to direct outreach and safety-related educational and efforts;
3) Conduct focused outreach briefings to share analysis data with key campus stakeholders;
4) With the HRPP, develop and disseminate best research practice training and information; and
5) Provide ad hoc, on-site evaluation and consultation for clinical researchers and their support personnel.

Conclusions: The addition of a comprehensive, risk-based analysis component to the existing postapproval oversight for human research protections facilitates the implementation of a long-standing University-wide subject injury policy and significantly augments efforts to protect the safety and welfare of subjects. By using case and incident-based trending of past subject risk events to guide education and training for investigators and key research personnel, UCSF will be able to learn from its experiences, reduce research risks and lay the ground work for development of benchmark standards to guide research safety efforts campus-wide. In this way, the wide ranging scope and framework of the UCSF Clinical Research Risk Management program may serve as a model for other UC campuses and as well as other large institutionally based clinical research enterprises.
Development of an Electronic Data Collection Tool to Improve Internal IRB Quality Assurance
Authors: Cheryl Forst RN, BSN, CCRP; Eanass Fahmy, BS, MS; Paula Bistak, RN, MS, CIP

Background
The Human Subjects Protection Program (HSPP) of the University of Medicine and Dentistry of New Jersey (UMDNJ) already had a long standing quality assurance and improvement program for auditing its research studies. However, audit of the Institutional Review Board (IRB) was usually a secondary part of this process. As we sought to expand our program to include a formal evaluation of the IRB, we wanted to develop a procedure that was: systematic, comprehensive, specific, measurable, and efficient.

Description of Program
Our informatics specialist developed an electronic form that would respond differently based on the user’s input. It included conditional formatting, optional and repeating sections, and/or programming elements. As form development progressed from original concept to final version it was tested and re-tested to establish a level of comfort with auditors. Further development would look at only specific sub-categories. Examples of specific sub-categories included: assents, vulnerable populations and drug or device studies. Utilizing both the long and short version of the form will successfully contribute to the quality assurance and quality improvement program. The task of reviewing compliance within the IRB would now be electronically captured and used to validate what had only been subjective findings in the past.

Additional Information
This poster was awarded Best poster of the year at SRA 2008 Annual Conference at National Harbor, Maryland.
Development of an Efficient and Effective System for IRB review of Non-Exempt Quality Improvement Projects
Authors: Roger Wilson, MD; Ann Rodavitch, MA; Katherine Fain, MPA; Collette Houston; Margaret Isaacs

Background
The determination of what types of quality improvement (QI) projects require oversight by the IRB has been unclear. During 2008, Memorial Sloan-Kettering Cancer Center (MSKCC) evaluated our current quality improvement program to develop guidelines and process for when such research requires oversight by the Institutional Review Board (IRB). The goals of the program were to:
- Develop criteria for what may constitute quality improvement projects requiring oversight by our local IRB;
- Develop a system for capturing these projects and redirecting them to the IRB;
- Ensure that the IRB reviews were complete and fully compliant with all regulations; and
- Ensure that QI projects requiring IRB oversight can efficiently work through the approval system.

Description of Program
To achieve these goals, a working group comprised of members of the IRB, the MSKCC QI program and the Office of Clinical Research (OCR) met to discuss and develop the guidelines. The working group did an extensive review of the current literature and guidelines on QI projects from the OHRP and other academic centers. After this review, proposed guidelines were developed and compared against current QI projects to evaluate the potential impact of the proposal. The resulting change in process included:
1) Standard protocol template for non-exempt QI projects;
2) Fast-tracked review of QI projects which skips normal subcommittee review and proceeds directly to IRB;
3) Creation of an expedited review at the IRB for these projects (expedited reviews for other new submissions are not permitted currently);
4) Posted guidelines on the QI website for assistance on the determination on when a project requires IRB review;
5) IRB membership which includes representatives from the QI program at the Center;
6) Training of staff;
7) Ongoing support of investigators through the Office of Clinical Research Protocol Development Office; and
8) Periodic reevaluation of the program.

Before implementation of the new process, several steps were taken: QI projects were pilot tested using the new system, the MSKCC Protocol Information Management System (PIMS) which is the IRB paperless database and document management system was modified and the IRB members, office and investigators were trained. The resulting process allows for a streamlined and effective mechanism to ensure that non-exempt QI projects are reviewed at the IRB.
Elements of a Successful Consent
Authors: Mary Ellen Cadman; Julie Brinell-Karabelas; Carol J. Squires; Katherine J. Whorton; Maria Rita Vieira; Maryland Pao; Barbara Karp

Problem/Issue Statement
To train investigators, research staff and clinicians on how to conduct an appropriate, effective and successful consent process.

Description of Program
Under the auspices of the NIMH Office of the Clinical Director, the Human Subject Protections Unit (HSPU) developed a course that provides training to investigators on how to ensure informed consent of research participants. This program includes the following elements:

- Element 1: Awareness & Understanding of Process Defines informed consent, who may obtain informed consent, who may give consent and assent, who may be surrogate decision makers, and identifying the concept of therapeutic misconception.
- Element 2: Subject’s Capacity To Give Informed Consent Differentiates between competency vs. consent capacity and reviews facets of capacity, the elements of a capacity assessment, and what can impair capacity.
- Element 3: Structure & Format Reviews the required elements of the informed consent document and special processes for the blind, non-English speaking and telephone consents. Presents informed consent as an ongoing dialogue between researchers and subjects.
- Element 4: Scaffolding & Context – Provides guidance for conducting the consent process: consent preview, document preparation, differentiating research vs. clinical care, presentation style and language, body language, consenting one subject to one consent at a time, and the consent environment and timeline.

Program Evaluation: This program is evaluated by pre-and post-course tests to determine if educational goals have been met; Feedback is solicited from attendees

Future Use: A consent training videotape is nearing completion The course is being offered to other NIH intramural institutes.

Suggestions for implementation at other sites: This best practice serves as a guide for other research venues and can easily be implemented with existing resources.
Empowering Populations to Understand Clinical Trials
Authors: Jillian Gardner; Harriet Etheredge; Anis Keshav (With acknowledgements to Prof Ames Dhai)

Background
The value of clinical trials as the optimum methodology for the testing and evaluating new treatments and medicines is well recognized. Progress in science has resulted in the development of innovative medical treatments, many of which could be beneficial to people living in low-income countries. In recent years, South Africa has become a sought-after venue for conducting health research that could lead to the development of some of these innovative new medical treatments. South Africa provides a particularly unique research environment encompassing high technological medical expertise and infrastructure and a significant burden of disease. The racial - cultural diversity provides an opportunity to investigate racially specific disease traits, whilst the migration of people (internally and cross-border) provides a wealth of patients with whom to investigate emerging and re-emerging diseases.

The scientists who conduct clinical trials are bound by the requirements of evidence-based medicine and the ethical conduct of research. Various codes and guidelines for research ethics dictate that all research involving human subjects should be conducted in accordance with four basic ethical principles, namely: respect for persons; beneficence, non-maleficence; and justice. Nevertheless, increasing research activity, competition in research and the attractive research environment may sometimes result in dishonest and fraudulent practice. Large portions of the South African population are illiterate, unemployed and live in poverty. Their typically dire socio-economic circumstances make them vulnerable to abuse and exploitation. Persons with limited education or illiterate people may find it difficult to understand informed consent information. Moreover, people with fewer economic resources who may have limited access to health services may see their participation in a clinical trial as the only opportunity to obtain needed health care. More often than not, it is the poorer people who are more prone to ill health (than their wealthier educated counterparts) who are invited to participate in clinical trials.

Because of the possibility that research could be misunderstood or abused, prospective participants need to be protected and must understand what may be expected of them and what will happen to them if they elect to participate in a clinical trial. The informed consent process is one example of how participants are protected. It is a universal requirement that prospective participants receive and understand all important information through the informed consent process before deciding to participate in a clinical trial.

Description of Program
Recognizing the high value that is placed on the notions of voluntary participation and the likelihood of potential rights violations in the context of clinical trials (due to researchers being more knowledgeable and acting as primary sources of information and education for prospective participants); the Steve Biko Centre for Bioethics of the University of Witwatersrand, in collaboration with the South African Medical Association and the World Medical Association, with sponsorship from Pfizer (External Medical Affairs, International) developed the “What it means to be part of a clinical trial” Talking Book. The format of the talking book is one which can have a high impact in populations where literacy levels are low. The book has vivid illustrations and push buttons by means of which the text on each page can be heard. Thus there are three sources of information in the book: read, heard and seen.

The talking book is an innovative way to share information given the language and literacy concerns that could compromise people’s understanding of clinical trials. Its primary aim is to prepare and inform individuals and communities in South Africa about clinical trials and about the roles and responsibilities of participants. This will empower them to make informed decisions about participation in clinical trials and have a stronger voice, before, during, and after, the research process. Following initial research into the effectiveness and ease of use of the talking book, it is hoped that the book will be translated into other
languages and distributed widely at international level. The book is specifically aimed to empower those in developing countries where literacy levels are low. Distribution would thus target these countries where the book will have maximum impact.

The Talking Book is being evaluated by means of a pilot project in South Africa in May and June 2009. The impact of the book, including its contribution to the understanding of research participants, will be assessed in this study. The ease of use of the book will also be evaluated. Further evaluations may be undertaken subsequent to the pilot study should these be necessary. It is hoped that the book will be widely distributed at – amongst others - primary health care centres and waiting rooms. As the book is a step prior to any clinical trial enrollment, it is important that those who might participate in a clinical trial have pre-trial access to the book. This will ensure that participants, when enrolled, would already be aware of their rights. Ideally, the book should be endorsed by policy makers in the country and become part of a national example of best practice.
Enabling Excellence in Human Subject Protection Across the U.S. Department of Energy
Author: U.S. Department of Energy, Human Subjects Working Group

Background
The U.S. Department of Energy (DOE) has over 25 facilities that conduct an uncommon spectrum of human subject research in the U.S and internationally. Identifying projects with and ensuring protection of human subjects is compounded by the variety of communities where these facilities are located. Since much of this research is quite different from that performed at hospitals and universities, the wisdom and experience shared at PRIM&R conferences often is not directly applicable to DOE research. Still, all human subject research conducted at DOE institutions, funded by DOE, or performed by DOE employees -- including classified or proprietary work -- must comply with federal regulations and DOE requirements. Accordingly, mustering and distributing resources tailored to individual DOE site needs is a formidable challenge.

Description of Program
Inspired by PRIM&R, the Human Subjects Working Group (HSWG) is a consortium of the DOE Office of Human Subjects Protection (OHSP) and IRB administrative staff at DOE sites that provides opportunities to share knowledge and experience in addressing issues unique to human subjects research within the DOE community. The HSWG has grown from a seedling into a solid oak tree providing ready and equal access to considerable resources regardless of site location, number of protocols, or budget. The vision for the group -- to advance the highest ethical standards in the conduct of human subject research within DOE -- is embraced as an ongoing quest and goal. The group meets twice a year for discussions of relevant topics. Monthly conference calls provide an opportunity to share issues requiring more immediate attention. This regular contact fosters interaction between members when specific issues arise. Relevant literature and educational materials are disseminated to the group via email. The HSWG has produced a variety of educational and information materials that address specific needs within the DOE community, sponsored a conference focused on community members which has grown into a 275 member listserv, and maintains a publicly available data base of all non-classified human subjects research conducted by, for, or at DOE facilities.

In 2009, DOE remodeled its concept for and practice of reviewing Former Worker Studies by changing from review by individual DOE site IRBs to review by a Central Department of Energy IRB. This new concept is intended to streamline IRB review and assist DOE with more effectively and consistently managing the numerous ongoing former worker projects within the DOE laboratory system. For similar reasons, the DOE Central IRB approach is being considered for application to other projects, potentially including the health impacts of exposure to nanomaterials and other evolving research topics.

Additional Information
The HSWG has the flexibility to deal with and rapidly address emerging issues. New members are added as individual DOE sites encounter issues related to human subjects research. As PRIM&R did for us, the HSWG could serve as a model for communication and education among any group of IRBs with a common set of issues related to human subject research.
Enhancing Audit Effectiveness: Development and Implementation of a Web-based Human Research Compliance Database
Authors: Alyson Hettenbach; Nancy M. Pultorak; Ann Sieber; Greg Barendt; Gregg Fromell

Background
Efficient and effective information management of human research audit findings is important to the disposition, management and follow-up of compliance findings, as well as tracking of regulatory compliance over time. However, commercial information system applications designed to collect and manage audit findings are either not designed for human research audit programs, or are too costly or complex to be feasible in an Academic Health Center (AHC) setting. Generic databases, such as MS ACCESS, do provide an affordable option, but scalability, number of concurrent users, and ability access remotely, introduce important barriers to efficient use of such applications.

Description of the Program
The Office of Human Research (OHR) and the School of Medicine Information Services (SOMIS) collaborated to develop a web-based application to manage the findings from the OHR human research auditing program and to replace a legacy application created in MS ACCESS. The development process began with the creation of a comprehensive list of user requirements that was also informed by experience with the legacy system. The goal was to provide a web-enabled Oracle database to input and manage compliance findings, functionality for project and workflow management, and an interface to enable investigators and research teams to directly respond to audit findings within the application. A prototype was developed to test proposed functionality. Auditors from the OHR Research Compliance Team (RCT) provided user testing and validation, and feedback to further evolve the application.

The newly developed compliance database is accessible via commonly available web browsers and protected by institutional server security and user authentication. Data feeds from institutional data systems automatically input information on research studies and associated investigators and coordinators. User access and functionality are assigned by the OHR RCT supervisors. Project and workflow management permits auditors to optimally manage their projects and for supervisors to easily oversee and manage workflow. The system includes an electronic audit trail, and also provides automated quarterly and annual compliance reports.

Program Evaluation
Application development began in January 2008, and the new system was launched January 5, 2009. It is an essential aspect of the OHR auditing program, and has performed successfully.

Next Steps
Further integration with other data sources, additional reporting functionality, several enhancements to the workflow, and ability to track more detailed information on studies conducted by faculty with IND/IDE responsibilities are also planned.

Suggestion for Implementation at Other Sites
A project leader with in-depth knowledge of the auditing program, project management, and workflow, as well as an experienced software development programmer.
Enhancing Efficiency in a Compliance Oversight Program
Authors: Jessica Randall, MA, CIP; Heather Butts, JD; Monique Superville, MA; George Gasparis

Background
For several years, Columbia University (CU) has had a comprehensive Compliance Oversight Program (COP). The mission of the program is to identify, evaluate and correct non-compliance as reported or detected from any potential source. The program is managed by the Compliance Oversight Team (COT), which reports to the CU IRB Office. Five Institutional Review Boards (IRBs) (4 at the Medical Center and 1 on the main campus) are responsible for overseeing approximately 2,500 active human subject research studies. The ability to identify, investigate, track and close compliance cases in a timely manner poses as a challenge especially in a large two-campus institution with a diverse research portfolio. Another challenge is the prioritization of new incoming cases. Multiple tools/processes have been developed and implemented over the past year to facilitate the management of the program.

Goals: (1) Guide researchers on how to obtain and maintain compliance through customized corrective action plans, education and training, and follow-up oversight monitoring, as appropriate (2) Manage compliance cases in a manner that enhances efficiency in the investigation of noncompliance by using flow charts, improving tracking systems and documentation, improving communication, and reporting of findings.

Description of Program
The COP currently manages: 1) investigations of alleged non-compliance; 2) not-for-cause audits; 3) monitoring of corrective action plans; 4) review of external oversight reports/FDA audits; 5) review of subject complaints; 6) OHRP/FDA investigations; and 7) all reporting requirements to regulatory agencies. At any given time, there are dozens of open compliance cases in various stages of review. Every case is initially entered into a database. The COT has incorporated tools to help the process, such as: an Allegation of Non-Compliance Reporting Form; audit worksheets; flowcharts of the process for each type of case; and a database for tracking all cases. The COT meets bi-weekly to discuss management of the program and individual cases. The flowcharts have been developed based on the experience of handling many compliance cases. By using the COT database in tandem, it is possible to prevent a particular case from remaining in one step of the process for too long. The flowcharts are clearly posted in the COT office as a constant reminder of the work flow for a given situation. The CU IRB has begun collecting metrics which will be analyzed for trends and used to evaluate processes. The flowcharts and tools can easily be tailored to other institutions to fit their specific needs and goals.
Ensuring Quality Assurance: Educating, Not Policing
Authors: Linda Furlini, PhD; David McLauchlan, MSc

Background
Unfortunately, good ethical practice is often understood as an issue of compliance with regulations, laws, standards and policies. Therefore, investigators and research staff often perceive QA oversight as threatening, policing and control mechanisms, instilling fear and prompting avoidance. Such negative perceptions create unfavorable environments that inhibit opportunities for learning. The QA and Education Program at the MUHC was designed to overcome such perceptions through its educational focus. Threatening references to “auditing” and “monitoring” were removed from QA policy documents. These changes were not merely an exercise in semantics. Another change to the QA policy excluded study sponsors from attending study reviews (Quality Improvement visits) or having access to the findings. This change encourages investigators and research team member to regard the reviews as educational activities rather than regulatory ones, conducive to greater learning. They feel at ease asking questions, discussing pertinent ethical issues and sharing findings with colleagues. These and other aspects of the program foster a supportive and collegial environment that advances the program’s mission, which is to promote a culture of ethical practice. This program’s educational focus has generated positive outcomes by increasing knowledge and interest in research ethics.

Description of Program
The program is composed of two components: quality improvement (QI) visits – REB approved studies are reviewed randomly or upon request when misconduct is suspected. Notwithstanding the educational focus of these visits, serious cases of misconduct or deficiencies uncovered will be reported to designated authorities as per our policy; and educational activities – These are tailored to meet general and specific needs, including one to one consultations, educational sessions, on-line modules, conferences and professional development for members of the research community (REB members, investigators, study coordinators, members of study teams, students, residents and the general public). Through a reiterative process, each component informs the other.

Evaluation of program: Evaluation tools in the form of questionnaires were developed for each component of the program. The findings from the QI visits were generally positive, but a wide range of observed deficiencies and variability in work quality was observed. The educational activities were well received, however, better ways to assess the diversity of educational needs is still required. The findings are used to modify and further develop both components of the program. The QA and Education Program is successful because it identifies positive and suboptimal ethical practices; prevents serious ethical violations; and promotes learning about emergent ethical issues. The results indicate that an educational focus should be a fundamental aspect of any Quality Assurance Program.
Evaluating International Collaborators' Training Needs for Capacity Building in Research Ethics and Responsible Conduct of Research (RCR)
Authors: Elizabeth Heitman, PhD; Ruth Ellen Bulger, PhD

Background
US researchers can help develop and implement strategies to build local capacity for ethical and scientific review in the international settings where they work. Colleagues' research collaborations in Latin American have twice prompted invitations for us to augment local educational efforts in research ethics and RCR, and provide practical training in ethical review. In both instances our group established collaborations between investigators and ethicists in the US and the host country, and developed successful NIH-funded education and training programs. This presentation develops two case studies describing a key step in the collaborative education process: assessment of the particular questions faced by local researchers and how to achieve their intended goals together.

Description of Program
The initial challenge in each host country was to accurately determine how best to help achieve the specific goals of the local research community. In each of our case studies, the crucial first step was a series of meetings to hear both formal testimony and informal anecdotes from as many interested parties as could be scheduled (including members and staff of existing research ethics committees, university-based investigators, hospital-based investigators, representatives of various governmental agencies and NGOs, and academic ethicists), and site visits in which collaborators became acquainted and observed the research environment.

At each meeting, we administered a survey of the local group's interests and self-reported knowledge and experience in research ethics, seeking to identify issues they wanted discussed (and at what level), what skills they wanted to increase (and to what level), and personal goals for training. Following the site visits, the collaborative team formally discussed the best ways to meet the local research community's stated goals and other perceived needs. Only after examining this in-depth information – some of which was unexpected and even surprising, did we plan the agenda for the education and training program in research ethics and RCR. Far more than the team's academic expertise or general knowledge of what local researchers wanted and needed, this deliberate assessment shaped the resulting educational program to meet more carefully identified targets. The active listening that these preliminary sessions encouraged made the resulting education programs both focused and responsive, and allowed us to build mutual capacity through collaborative educational activities.

Additional Information
Although the educational collaboration from the first program has ended, the research ethics infrastructure in the first host country is operating well. The second program, still in process, has seen the partnership grow and valuable new opportunities develop.
Exception From Informed Consent Projects Conducted for Emergency Settings (EFIC)—The University Of Michigan Experience
Authors: Belinda Adamson, BS, MEd, CIP; Jan Hewett, JD

Background
In 1996, the FDA and HHS adopted regulation 21 CFR 50.24 which created a narrow exception to the requirement to obtain and document informed consent from a person or his/her legally authorized representative prior to enroll in a clinical research project. Accordingly, the Federal government permitted Institutional Review Boards ("IRBs") to approve certain research protocols in which investigators reserve the option to enroll subject who, due to their medical condition, are unable to consent to participate at the time of enrollment. Many Academic Medical Center’s ("AMCs") who formerly had policies that prohibited such research revised these to permit the conduct of Exception From Informed Consent ("EFIC") projects. The University of Michigan Medical School ("UMMS") was one such institution. Specifically, the UMMS reversed it former decision and began conducting EFIC research in 2007. As a result a series of policies and Standard Operating Procedures ("SOPs") for investigators, IRBs and community members to review when designing, implementing, and approving EFIC trials were developed.

Description of Program
This poster will outline the policy and SOPs drafted for EFIC trials and discuss the sequence of events that must take place to approve an EFIC project. Description of Program: At the UMMS the EFIC Study Process is comprised of seventeen steps. Each step will be described in the poster. For example:
• A subcommittee is formed consisting of the IRB Co-Chairs, IRB Director, IRB Regulatory Analyst, Faculty members with the intervention expertise and a community member to review the community consultation plan. This committee meets with the investigator to decide to support the community consultation plan.
• The investigator submits the electronic human subject research application for ancillary committee and convened board consideration.
• The subcommittee and PI meet to review the consultation plan summary. If the subcommittee feels that the community- at- large has be informed and supports the proposed EFIC study; the project continues the review process.

Evaluation Method: The process has undergone a quality improvement and assessment to measure the effectiveness of the EFIC documents and approval process.

Suggestions: Institutions are encouraged to develop effective policies and procedures when conducting EFIC research.
Expanding IRB Member Education: Incorporating IRB Staff Training Into IRB Member Educational Initiatives
Authors: Tracy Ziolek, MS, CIP; Megan Kasimatis Singleton, JD; Yvonne K. Higgins, CIP

Background
IRB member education is a vital part of IRB operations. Our goals in developing an IRB member educational series were to create an ongoing process, that is both responsive to the educational needs of members and current, to inform members of emerging regulatory and ethical issues. This program serves a dual training purpose, as the educational materials are developed and presented by the IRB staff.

Description of Program
This program was designed to incorporate training for IRB members into the IRB meeting by offering topic-specific presentations to each IRB Committee as an official agenda item. The presentations were drafted by the IRB staff; topics were chosen based on emerging guidance and common issues seen at IRB meetings. A list of 12 topics was initially developed to account for one year of training. Examples of topics include IRB decision making and the criteria for approval, vulnerable populations, reviewer presentations and IND/IDE regulations. To enhance the expertise of IRB staff, each staff member researched and developed at least one presentation. Prior to finalizing the presentations, each topic was presented for feedback to the staff and reviewed by the Executive Director. Each IRB Administrator then presented the monthly topic to their Committee and fielded any questions.

Outcome: While the educational series is ongoing, the positive effects are already notable. IRB members are incorporating the information provided in the presentations in their reviews and discussions during the meeting. The IRB staff has found the experience rewarding; the training program enhances staff knowledge of IRB policy and processes and empowers staff as valuable resources for their Committees as they take on this instructive role.

Suggestions for future usage: The current program includes a topic list that extends to 18 months of training; this list will be updated as regulatory and policy changes call for new training opportunities. Every 6 months, IRB members and staff will be surveyed to evaluate the success of the program and collect suggestions for future presentations. The feedback from these evaluations will also be used to identify areas for improvement in these presentations.

Suggestions for other sites: This program is easy to initiate at any site. IRB staff should convene to develop topics specific to the educational needs of their IRB members. For institutions with fewer Committees, IRB staff may rotate as presenters. Presentations should be added to the monthly agenda as an action item to encourage member participation.
Experience with IRB Review in Data Sharing for Genome Wide Association Studies: From the eMERGE (electronic medical records and genomics) Network
Authors: M.E. Smith, J. H. Hellyer, A.A. Lemke, C. McCarty, K. Ehrlich, E. Larson, M.A. Bassford, L. Dressler

Background
The recent NIH policy outlining expectations for federally funded investigators to share research data from genome-wide association studies (GWAS) has moved the issue of “data sharing” to the forefront of genomic research. For many IRBs, the dialogue related to the ethical and regulatory issues surrounding data sharing has just begun. The eMERGE Network is a national consortium formed to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record systems for large-scale, high-throughput genetic research. Through this network, we have had the opportunity to interact with our IRBs to address issues of review of GWAS studies, including data sharing and being in compliance with the NIH GWAS data sharing policy. We report our preliminary experiences here.

Description of Program
The NIH Data Sharing Policy strongly encourages federally funded investigators performing GWAS to submit data for sharing with approved researchers worldwide. Procedurally, this requires IRBs from submitting institutions to review and verify that a study meets NIH requirements for data deposition into a federally controlled database called dbGaP. Institutional certification indicating compliance with the requirements must be obtained for all datasets submitted to dbGaP, including any limitations on use of the data. All eMERGE sites will submit phenotypic and GWAS results to dbGaP. Recognizing that many ethical and social issues surround large-scale genomic research and data sharing, eMERGE includes a focus on ethical issues through the Consent and Community Consultation (C&CC) Workgroup.

Interaction with IRBs: eMERGE Network researchers have interacted with their respective IRBs to review GWAS protocols, including consent forms and data use restrictions for depositing data into dbGaP. Our preliminary experience indicate that all IRBs have been supportive of working with researchers on GWAS studies and data sharing yet many are unfamiliar with the nature of GWAS and NIH policies related to data sharing. With the exception of one site, no specific process was in place for review of GWAS or obtaining institutional certification. In addition, we observed differences regarding IRB requirements for use of existing specimens and data. At one site, the use of specimens for GWAS was not considered human subjects research, while at another site IRB review determined that language specific to data sharing was inadequate and reconsent for dbGaP sharing was required.

Significance: Based on our preliminary experience we identified several opportunities to facilitate the interaction between GWAS researchers and IRB review, including education and development of consistent policies. We will present the various methods used to address the educational and procedural issues by eMERGE Network investigators and their ethics consultants.
From Shut Down to AAHRPP Full Accreditation in 10 short Years: A Case Study of the Operational & Organizational Changes at the DUHS IRB

Authors: Charlotte Coley, MACT, CIP; Chelle Yin, RN, MSN, CIP

Background
In the 10 years between the OPPR shutdown in May 1999 of the Duke University Health System (DUHS) program to its AAHRPP full accreditation in 2009, the program went through a number of operational and organizational changes to transform the program. Duke University Health System's journey through these changes may offer ideas that would help other institutions. Focus on hiring staff and making changes: work flow standardization, staff training, research community and IRB member education.

Description of Program
At the time of the May 1999 shut down, DUHS had ~1900 active studies, one IRB, one Chair and one Vice Chair, a staff of 2 FTEs and was supported within the Grant and Contract Office. Today DUHS has ~4800 active studies, 9 IRBs (8 that each meet monthly); 4 Chairs, 6 Vice Chairs, a staff of 18 FTEs and is an independent department. Significant change happened in the past 10 year period to transform the IRB to its present state. The process was as close to starting from a clean slate as possible and still have an existing IRB program. Everything needed to be created from the ground up, organizational structure, operational procedures, SOPs, job descriptions, equipment acquisition and office configuration. While a challenging task, it was also an exciting opportunity for re-birth of a program. The structure had to be created upon which the renewed review processes and institutional culture could grow.

This poster will address those organizational and operational tasks and document that growth over the past 10 years. Issues to be addressed are:

1. Work flow: a comprehensive look at the regulatory charges to a human research protection program to identify the necessary tasks and staffing needed to accomplish them. Design of a work flow that would grow from a paper process to an interim semi-electronic process to a full blown electronic IRB. The need for the development of standard operating procedures and processes; again from elementary to those needed for AAHRPP accreditation.

2. Staff training: the first issue was to define what staff skills were needed to accomplish the required tasks of the IRB, then creation of a job description, and hiring of staff (at a time when many did not see the IRB as a desirable place to work). The focus was finding staff with analytical and communication skills to both provide the necessary administrative support to institutional researchers and able to do the work of the office. A new position of writer was created to do minutes, review consents and assist researchers in the development of their own consents. It was important to create various levels of jobs within the office to provide opportunities for advancement. IRB staff often requires a significant on-the-job training investment and once trained it is important to retain that staff for as long as possible.

3. Education programs for researchers and IRB members: The third leg of this program re-design was the development of an expanded education program that would raise the level of awareness across the institution and driving a significant increase in compliance by putting a greater emphasis on training for everyone involved—researchers, research staff, IRB members and staff. These operational and organizational changes ensure that our research is of the highest quality: that it is ethical, has scientific merit, and protects participants and fosters the public trust that is critical to the future of research. They provided the foundation for the construct of a program that becomes a more cohesive HRPP enabling the institution to better protect research participants and advance research more efficiently and effectively.
From the Crows Nest: Oversight and Monitoring in the Department of the Navy Human Research Protection Program
Authors: Marianne M. Elliott, MS, CIP; William M. Deniston, PhD.

Background
The Department of the Navy Human Research Protection Program (DON HRPP) oversees and monitors its institution-based HRPPs. The Navy needed to create a systemic, functional, yet flexible approach to monitoring a wide variety of research that supports war fighters and their families.

Description of Program
The DON HRPP oversees and monitors its institution’s human research protection programs including: reviewing institutional policies and procedures; reviewing IRB meeting minutes; post-approval review of research protocols; and conducting site visits. To establish a uniform process the DON HRPP created criteria-based guides to review IRB meeting minutes and research protocol submissions. The IRB meeting minutes guide includes a section to determine if the IRB meets regulatory requirements and a section to identify research protocols for review and to gain a sense of the overall functioning of the IRB. There are four reviews guides for research protocol submissions: initial review; continuing review, final report, and reinstatement review; amendments; and unanticipated problems and adverse events.

Each review guide contains an administrative document verification section and a regulatory section. The regulatory section is divided into two aspects: review of the research protocol submission and an assessment of the IRB’s determinations. The DON HRPP uses the results of reviews to develop policy; target education and training efforts; and plan site visits. The DON HRPP also shares the results of the reviews with the institutions. The ultimate goal is to provide evidenced-based feedback to Navy institutional HRPPs in a collegial manner to result in improved research protections.

Program Evaluation: While most of review guides themselves are still under evaluation, the approach has resulted in some anecdotal observations: (1) an increase in interactions between the DON HRPP and institutional HRPPs; (2) training efforts designed to align with institutional needs; and (3) areas for further guidance have been identified.

Future Uses: The review guides for IRB meeting minutes and research protocols submissions can be used by other organizations responsible for oversight and monitoring. Additionally, institutional HRPPs can use these as self-assessment tools.

Disclaimer: The opinions expressed in this presentation are those of the authors and do not reflect the official policy of the Department of the Navy, the Department of Defense, or the Unit.
Getting the Message Out: Innovative Training Methods for IRB Members
Authors: Rebecca Flores Stella; Nancy Danielov

Background
The question of how to appropriately educate IRB members is a challenge left to each institution. While it is generally agreed that the education and training of IRB members is an important undertaking, there is a wide variety in the materials and approaches used. Programs continue to wrangle with the question of how to best present what members need to know in order to understand the importance of their responsibilities. In response to this challenge, the Office of Research Compliance and Quality Improvement developed a comprehensive IRB Member Education Program that utilizes a variety of approaches to disseminate the importance of “doing it right, together.”

Description of Program
Initial training includes an overview of the IRB process, regulations and guidelines pertaining to research involving human subjects, and institutional policies and procedures. Members receive educational materials in written and electronic format. IRB members are required to complete online educational modules that are specific to human subject issues at Cedars-Sinai Medical Center (CSMC). The modules include an interactive assessment that requires members to consider common scenarios that arise in the review of submissions. IRB members are encouraged to attend workshops and meetings focusing on human subject protection, including the CSMC IRB Grand Rounds. IRB Grand Rounds are educational sessions designed to provide members of the research community with exposure to current “hot topics” by inviting national leaders in the arena of human subject protections to speak at CSMC. IRB members are routinely provided with articles from scientific literature and appropriate educational materials that are stored electronically for easy future reference.

A routine follow-up assessment is conducted with each new IRB member upon their completion of six months of service on the IRB. As part of the follow-up, the IRB Education team obtains feedback on the new member’s performance from the IRB Chairs and staff. Once this information is collected and reviewed, the IRB Education team assesses the need for additional training. A meeting is scheduled with the IRB member to review the compiled information. The member is encouraged to provide feedback about IRB experiences to date. The follow up training is documented in a brief summary to be sent to the IRB member, IRB Chair, IRB Executive Chair and the Director of Research Compliance and Quality Improvement.

Evaluation of the Training Program and Feedback Received: Effectiveness of the training program is assessed by the contributions made by each member. On an annual basis, IRB Members participate in an anonymous peer evaluation process. Members are asked to rate their peers in regards to familiarity with regulations and policies, and their ability to apply that familiarity in the review of IRB submissions. The evaluation includes input from the IRB Chair. The annual survey asks the respondent to comment on possible training needs for their co-members. A summary of feedback received is forwarded to each member’s Department as a report of their contributions to the IRB.

Suggestions for Implementation at Other Sites: The components of our IRB Member Education program can be easily implemented at any institution. Activities, such as IRB Grand Rounds, offer the unique opportunity for collaboration with other institutions. The IRB Member Evaluation Survey is an assessment tool that facilitates the annual performance evaluation of IRB members and the development of training initiatives that are specific to concerns raised by the IRB members.
Impact of Cultural & Educational Differences On Informed Consent Process In Liberia

Authors: James N. Kollie Sr., PhD; Jemee K. Tegli, BA; Stephen B. Kennedy, MD, MPH; Cecelia Morris, MSN; Ellen George-Williams, MSN; Edward Smith, MPhil

Background
About 65% of the population in Liberia is functionally illiterate. Yet, the administration of an informed consent process is a major requirement for the enrollment of participants in research studies. This is particularly so, when such studies are being undertaken in a post-war developing country such as Liberia where there are limited resources for adequate protection of human subjects. Strategies such as effective user-friendly communication techniques, cultural sensitivity and community norms, inputs of key informants and target population, hiring of community workers, adequate training of field workers, and the availability of relevant resources can lead to great success in the implementation of the informed consent process in such settings.

Description of Program
This study is a case study based on Liberia. It is designed to redress this critical aspect of the current state of near ignorance about data gathering process from second language learners in Liberia. The study will provide a critical assessment and suggest means on how the process of collecting data on informed consent process from second language learners required in research dealing with human subjects, be improved. Given the language problem as second language, one could attempt to use local language to train local people to understand what informed consent means. It is believed that many of the problems in Liberia during the past years were to some extent, due to misinterpretation of ideas of others. They attribute this to the fact that a majority of the people in parts of Liberia speak only in their dialects or vernaculars. For example, when government policies are taken to the people in those areas, they are often relayed by interpreters who may not have understood the message properly and therefore translate wrongly thus leading to misinformation. Poor comprehension arising from language barrier such as in Liberia where quite huge majority of the population speaks English as second language is a case in point. Effective communication can lead to great success. It is intended to address similar problems that may occur with other human subject studies that will involve non-English participants in other parts of Liberia.

Additional Information
Some acts cannot legally take place because of a lack of informed consent. In cases where an individual is considered unable to give informed consent, another person is generally authorized to give consent on his behalf, e.g., parents or legal guardians of a child. Language becomes a barrier and this need to be tackle for concise interpretation purpose.
Implementation and Outcomes of a Research Ethics Education Program for Cardiovascular Investigators
Authors: Professor David Solomon, PhD; Sara L. (Sally) Tobin, Ph.D., MSW

Background
Human subjects protection education that is tailored to specialized researchers and suited to their particular interests or research context may serve to improve their ability at addressing human subject protection issues that arise in their practice. However, there is a dearth of literature that describes specialized human subjects protection education, including issues related to development, delivery or evaluation. In 2004 we conducted a needs assessment among scientific members of a large health professional society with interests in cardiovascular health to determine their need for and interest in human subjects protection education, and preferred educational delivery method. Our study demonstrated significantly greater interest in some human subject protections topic compared to others, and that some interest differed by respondents’ professional affiliation or training. Subsequently, we used data from our needs assessment to develop a program of research ethics training for cardiovascular investigators, which was subsequently funded by NIH through 2010.

Description of Program
Our program consisted of fifteen educational modules on different topics, including, for example, statistical analysis, emergency research, subject advocacy, pediatric research, genetic research, and subject recruitment. Each module included reading materials distributed online, a didactic presentation, a related case study for discussion and problem-solving, and handouts. Topics were contextualized to cardiovascular research, but framing principles are widely applicable. For each course, course and speaker evaluations were collected, and a debriefing session conducted. Our intended outcome was a transportable, modular program of research ethics education that met the expressed needs of prospective constituents comprised of cardiovascular researchers and others (e.g., IRB members) with interests in cardiovascular research ethics and human subjects protection.

To date, eight courses each consisting of up to six modules have been delivered across the U.S., held on or near to major centers of cardiovascular research. Through our debriefings as well as evaluations, course participants expressed a high degree of satisfaction with our educational content, our delivery methods, and having met our educational objectives. Our methods and instruments are easily replicated by others who are interested in developing specialized educational programs in human subjects protection. Our educational materials are currently being prepared for online dissemination at no cost to end-users.

Additional Information
The goals of the proposed session are to (1) improve understanding of the challenges of human subject protection education environment for cardiovascular investigators; (2) describe development, evaluation, and instructional methodology of a cardiovascular disease research ethics educational program; and (3) provide an opportunity for sharing human subject protection education ideas and discussing related issues.
Implementation of the University of California System's IRB Memorandum of Understanding
Authors: Rebecca D. Armstrong, DVM, PhD; Lisa Voss, MPH

Background
As the number of collaborative multisite human research projects continues to increase, new models of IRB review are being explored. The University of California System and the Lawrence Berkeley National Laboratory have created a IRB Memorandum of Understanding with the goal of decreasing the number of UC IRBs that needed to review collaborative research taking place at multiple UC sites and thereby reducing the burden on principal investigators and increasing the speed of study implementation.

Description of Program
The possibility of a cooperative effort began with discussions amongst the IRB Directors of campuses with medical schools and with the assistance of the UC Office of the President in 2005 expanded to include the IRB Directors of all UC campuses and the Lawrence Berkeley National Lab IRB. After much discussion and negotiation, the proposed MOU allowing reliance on each others IRBs for new exempt and expedited studies was submitted to the Institutional Officials of each school for signature in March 2006. It was unanimously endorsed.

Program Description: The MOU delineates the responsibilities of the institutions and separates the IRBs into the Reviewing IRB or the Relying IRB but left out the details of how to implement the administrative processes. The IRB Directors reached consensus on a) documentation requirements; b) a MOU Application Form; and, c) a process flow chart. All three of these items have undergone changes and improvements as a result of our experiences. In 2008 the MOU was revised to include previously approved projects and in 2009 the MOU has been expanded to include full committee reviews along with implementing mandatory human subjects training for PIs to be able to submit protocols for review under the MOU.

Evaluation: Few objective measures exist of the success of the MOU other than the steadily increasing utilization of it by PIs. Systemwide there are approximately 100 Reviewing IRB projects; and, 125 Relying IRB projects however, UCSF estimates that the MOU saves their PIs approximately 137 hours in IRB preparation and review per project. An unanticipated benefit is an increased understanding of each others' policies, procedures and institutional climate – along with more cooperation between IRB offices. Future Directions: We are just beginning to apply the MOU to full committee reviews systemwide although UCSF, UCB, UCD and LBNL had been piloting full committee reviews amongst their campuses for almost two years. We are also exploring expanding the MOU to include collaborations where institutions outside of the UC System are involved.

Additional Information
While this has been a UC Systemwide effort, Ms. Voss and Dr. Armstrong have spent an enormous amount of administrative time on this implementation and their institutions, UCSF and UCB respectively, are by far the biggest "users" of the MOU process.
Improved Protocol Analyst Processing through the use of an Activity Guidebook

Authors: Dena Johnson, BS, CCRP, CIP; Becca DuBose, CCRP, CIP; Jan Zolkower, MSHL, CIP, CCRP

Background
Preparing protocols received by the Institutional Review Board (IRB) for review in a streamlined, consistent manner can prove challenging for an IRB with four committees that reviewed over 8000 submissions in 2008. The number of protocol analysts required to manage this endeavor can potentially lead to confusion and frustration for the IRB committees and the research community if there is not a consistent process in place to facilitate review of new studies and all subsequent submissions. In addition, communicating these numerous processes to protocol analysts who may be new to the department can prove extremely difficult without a written guidebook. Finally, knowledge regarding how to input data correctly regarding submissions and their status is critical in terms of ensuring data integrity.

Description of Program
At Vanderbilt University, information regarding specific database processes with regard to preparing submissions for review, in addition to the preparation of meeting agendas, minutes etc. requires detailed knowledge of the departmental database. Also, the department’s recent transition to a paperless IRB system, adds to the burden of the analyst with regard to ensuring data integrity for the IRB as well as other departments and the research community because of its transparency.

Analysts within the department have developed an Activity Guidebook which provides step-by-step instructions for preparing submissions for review. The guidebook includes information regarding any action that is required in the IRB database from processing new study submissions, to the preparation and distribution of meeting agendas and minutes, plus how to monitor each team’s outstanding work items within the database. This guidebook has become a vital tool for ensuring uniform processing so that the same information is communicated to the research community. The guidebook also allows flexibility in training for new analysts so there is a level of independent learning that can take place without another analyst overseeing every step.

Periodic updates are required as processes change and new enhancements to the database and electronic submission system are implemented. One experienced analyst within the department is charged with facilitating edits to the guidebook. Future updates at Vanderbilt will include instructions for compliance reviews and audits as the department automates this process.

The development of an Activity Guidebook can begin with simple process descriptions for new study submissions, continuing reviews, meeting agendas and minutes. As processes become more comprehensive, the guidebook can be expanded to include additional tasks and can become a critical element for staff training.
Improving Turn-Around Time for Initial IRB Review of Minimal Risk Studies  
Authors: Cerdi Beltre, CIP; Hallie Kassan, MS, CIP

Background  
Established turn around time goals for review of expedited and exempt studies were not being met. The initial response time for exempt studies was 10 business days (goal is 4 business days) and expedited studies was 14.6 business days (goal is 10 business days). The benefits of improving the turnaround time goals include: Increase new study submissions, increase customer satisfaction, prevent loss of funding, increase compliant research and increase patient treatment options.

Description of Program  
The “program” in this project was the process by which the IRB conducted reviews of minimal risk studies. An excel spreadsheet was used to track type of review (exempt or expedited), IRB study number, date of initial IRB receipt of the project, date of initial IRB response to Principal Investigator, and total number of business days that it took the IRB to provide the PI with a response. Each IRB staff member tracked their reviews and the data was used to identify the length of delays.

By meeting individually with the IRB Chairs and Office Staff, the causes of the delays in providing Principal Investigators (PIs) with the initial response were identified. These causes were assessed to identify the following improvements which could provide the highest benefit with the least amount of effort.

- Rotation of exempt studies amongst four (rather than one) IRB staff members for review,
- Increased use of all IRB Committee Members on expedited reviews,
- Develop reviewer sheet for expedited review to assist Committee Members,
- Develop office checklist to standardize initial review process,
- Established process for coverage when staff is out of the office, and
- One on one meetings with the director to hold staff accountable and provide education.

We also began publicly reporting turn around time frames on our website to increase transparency for the research community. After three months of program implementation the data was reviewed again. The average turnaround time for initial response on exempt studies decreased from 10.1 to 3.1 business days. The average turnaround time for initial response on expedited studies decreased from 14.6 business days to 7.5.

Future Program Usage: The project’s goal was to meet the established turnaround time goals 100% of the time. These were not met 20% of the time. The causes of delays were: staff issues, unexpected staff days off, IRB Committee Members not providing review in a timely manner, and lack of following process for staff vacation. The improvement plan will continue to be used within the IRB office and issues causing delays will continue to be addressed. IRBs may often struggle with balancing the demands of providing investigators with a timely review without sacrificing the quality of the ethical review. Using the currently available IRB Committee members, addressing the causes of delays at their sites, and simple tracking and evaluation of metrics can decrease delays in reviewing minimal risk studies. By decreasing IRB turn around time, researcher compliance with human subject regulations may be increased as the IRB process would not be prohibitively long.
Incomplete Disclosure: A Partial Truth  
Authors: Lee A. Booze-Battle, CIP; Terry M. VandenBosch, PhD, RN, CIP, CCRP

Background  
Ever since the 1963 Milgram “teacher-learner experiment” raised controversy, deception research has been a contentious topic of discussion for IRBs, investigators and ethicists. A less well known, and growing, subset of deception research, “incomplete disclosure” has received significantly less attention. Because IRBs with a biomedical profile see this type of study infrequently, education that clearly articulates a definition, ethical implications and justification of incomplete disclosure in the context of IRB review is useful. (new 1P) Deception studies are fairly common in behavioral research and, until recently, have been used less frequently in biomedical research. Deception study designs, including incomplete disclosure, are increasing in biomedical areas of psychiatry and neuroscience primarily because of advances in brain imaging technology. These advances allow investigators to examine neurological responses to stimuli such as expectations, attitudes, fears, phobias and simulated clinical encounters or treatments. However, neurological responses are more measurable when more strongly elicited using designs such as incomplete disclosure.

Description of Program  
This poster uses a case study approach to educate IRBs on ethics and on context for review of studies using incomplete disclosure. The case study presented is derived from an actual study that received full board IRB approval. A post-IRB approval review of the study triggered discussion, and stimulated a complete analysis and revision of IRB review for all studies using incomplete disclosure. The analysis included consideration of regulatory issues, scientific issues, ethics of participation, and study team characteristics such as research experience.

A program of didactic education focusing on deception studies, which included an emphasis on incomplete disclosure, was developed and presented to IRB members and staff. Program content was developed through ethical analysis of the incomplete disclosure study described in this poster. The content is applicable to IRBs at other institutions with researchers who submit studies in the areas of psychiatry and neuroscience.

Program Evaluation: Systematic changes to IRB review of incomplete disclosure and didactic education of IRB members and staff were evaluated through use of research evidence on participant effects of deception research and on ethical analysis of the study serving as the stimulus for change.

Limitations: This is a case study, an appropriate vehicle to describe events such as incomplete disclosure that occur infrequently. Any case study may be limited in its generalizability.
Informed Consent: Hollywood Style
Authors: Rebecca Flores Stella, CIP; Nancy Danielov, MA, CIP; Jessica Spotts; Keren Dunn, CIP

Background
The cornerstone of human subject protection relies greatly on an effective informed consent process. How can we best relay the importance of effective informed consent to all key players, i.e., research volunteers, research team members, and IRB members? Comprehensive training on the essential components of informed consent should address what information must be discussed; suggest methods for assessing the subject’s understanding of the information provided, and emphasize the voluntary nature of participation. We propose that educational initiatives are more effective when they are developed from data gathered from actual research participants. Is it possible to utilize quality assurance data to help to illustrate how the core protection of informed consent helps to ensure the safety and welfare of research participants?

Description of Program
The Quality Improvement Program at Cedars-Sinai Medical Center’s (CSMC) deploys several surveys in an attempt to collect data on the effectiveness of various programmatic initiatives. One of the tools developed by the program is the Research Participant Survey. Research Teams work in partnership with the ORC&QI to promote the survey to individuals who have completed participation in a research study. To date, 1338 survey packets have been provided to research coordinators for distribution to research participants. 594 surveys have been completed. The survey questions address basic demographics, the consent process, the experience of participating in the research study, and assess the individual’s overall satisfaction with participation in research at CSMC. Participants can either complete the survey in hardcopy or using an online survey tool. Survey administration is completely anonymous, but participants can provide contact information to receive a $5 thank-you store card.

Data from the survey is compiled and reviewed on a regular basis. Data from the 2008-2009 calendar year was analyzed with a focus on the participants’ impressions of the informed consent process. The data suggested that while overall satisfaction was high, there was room for improvement related to communication of the purpose of the study; the distinction of research procedures from standard care practices; information related to study logistics (e.g., when, where, how much); and issues related to billing and compensation.

The IRB Education Team used the data to develop several video vignettes where actual research team members and IRB members/investigators assumed starring roles as investigators and potential research subjects. Scenarios focused on the areas identified for possible improvement by the survey data. Vignettes were designed with the intent of providing examples of best practices in informed consent by allowing the viewer to “see a process in action.” Video participants reported increased understanding and empathy for the research participants whose concerns they represented, as well as for the research team members who are responsible for educating research volunteers. The video has been modified as an online module that is available for the continuing education of all research personnel. Impact of this training initiative will continue to be evaluated as part of ongoing administration of the Research Participant Survey.

Future Program Usage: The Informed Consent Video project is an example of how quality assurance data can be used to address issues that may arise in the day to day conduct of human research at your institution. Involving IRB members, members of the research community, and IRB staff in the development of the educational video was an effective means of communicating the important role of the informed consent process. We were fortunate to have a staff member who moonlights as actress/film maker by night, a common phenomenon in Los Angeles. In addition to the development of an innovative educational tool, this project demonstrated the benefit of allowing staff to explore how their outside
interests and passions can be applied to the protection of human subjects.

**Suggestions for implementation at other sites:** Best practices in human research protection programs have a strong focus on continuous quality improvement. As many institutions collect data on the outcomes of programmatic initiatives, it is important to understand how that data can be used to refine protections and offer site-specific training initiatives. Several low-cost options exist for the development and deployment of online survey tools. Finally, while it is helpful to have an eager thespian as part of your team, it is not a prerequisite for project implementation. Our video was taped using a standard digital video recorder and online “movie maker” software. Institutions needing technical support for similar projects are encouraged to research services available through your medical media department to help determine what tools are available.
Informed Consent – One Size Does Not Fit All
Authors: Carlotta M. Rodriguez, BS, CIP; Amy L. M. Lallier, BA, CIM, CIP

Background
Obtaining informed consent is a fundamental responsibility of investigators enrolling human subjects in research. Built upon the ethical concept of respect for persons, it is how we ensure that subjects know the inherent research risks and benefits, and have had the opportunity to weigh them. The consent process is dynamic, and should be built around the populations to be enrolled. As such, no one size fits all. The realities of time and money make individualized consent materials all but impossible. It is incumbent upon research professionals to develop flexible and varied consent documents and processes to ensure that the informed consent process is meaningful.

Description of Program
Our institution provides numerous resources to investigators, and has developed several unique consent processes in cooperation with and response to specific investigator needs. Most recently, our Human Subjects Protection Office, in cooperation with the Legal Department and Research Deans developed and implemented a Surrogate Consent Process following a re-reading of NJ state law. Working with our Cancer Research Center in the face of low enrollment per site and a plethora of languages spoken by potential participants, an additional consent provision, the designation of a bilingual consent aide, has been incorporated and evaluated as a consent tool. This process was audited by the Human Subjects Protection program to evaluate its utility in this population.

In addition to these special resources, our IRB office provides electronic consent templates to investigators addressing many different consenting scenarios and situations. Identifying populations in need of additional considerations and helping investigators comply with regulations while providing the best possible array of informed consent options to successfully communicate with their subjects is an ongoing and necessary component of all human subjects protection programs. In order to implement this type of activity at other institutions, it may be helpful to assemble key stakeholders in the processes of recruitment and consent to ascertain where they identify the greatest need for innovative consent development.
Innovation For Research-Oriented Educational Program About Research Ethics of Tokyo Medical and Dental University in Japan

Authors: Yuka Ozasa; Masumi Ai; Naoko Nii; Masayuki Yoshida

Background
Lack of e-learning system like CITI in Japan, we are now trying to educate seminars, lectures and individually services by our center's staff (4) to all researchers (1500) in our institution.

Description of Program
Recently, Japanese guideline for clinical research which makes new regulation clear, had been renewed some contents including compulsory education about research ethics. And some grants funded by government are getting required such certification about education for research ethics when they apply. Since 2008, our center had planned several seminars which provide not only knowledge but philosophy about protection of Human Subjects. At first, we gave lectures about six guidelines for research with Human Subjects in Japan to regulate IRB's function and the style of informed consent etc. Second, we told them important essences which guideline should be kept on their research, what point must be keeping treating Human Subjects on their research. Third, we had some messages how important to keep high value on both ethical and scientific side on their researches which lead fruitful research outcomes. With those trial seminars, their applications which became to IRB were much more smart and enriched. At the same time, we also tried to educate IRB's members about that helps them how to focus reviewing points and what to take role on committee using paper articles and literature on this subject. Of course, we also support individually via e-mail, phone and interviews. Additionally, we began to have some lecture about research ethics in all our graduate school. We also found out that most common useful materials for researchers and IRB's members were actual examples which made them to experience concretely and easily.

On those processes, we were helped by Sarah Putney who used be a director of HSA in Harvard school of Public Health and now in Emory University school of Medicine as IRB director. With her great help, we could understand why IRB's approvals were so quick with reliable review in U.S. Now we are trying to promote new original e-learning system such as CITI. Compared with CITI, our plan to create new e-learning systems might be much more not so explanatory but experimental focused on confirming their own research theme using Q&A lists which we stored from our past works as actual examples.

Our next step will be how to get working funds and human resources for keeping current quality on management of IRB function. Another mission must be to establish new association about research ethics where researchers and IRB members / operators will meet and talk together for sharing essence of problem solving like PRIM&R.
Institutional Compliance with 45 CFR 46.103(b)(2): Are We Doing Enough?
Authors: Keren Patricia Dimah, MPA, MPH, CIP; Eileen Yates, CIP; Tasha Osafo, CIP; Debbie Gibson Tice, CCRC, CIP; Don Workman, PhD

Background
HHS regulations at 45 CFR 46.103(b)(2) require that institutions provide meeting space and sufficient staff to support the IRB’s review and record-keeping duties. Review of the OHRP website shows that noncompliance determination letters have been issued to institutions that have failed to comply with this requirement. To ensure that our Human Subjects Protection Program is complying with this requirement, an anonymous online survey was administered to all members (alternate and regular) of the Institutional Review Boards. The purpose of the survey was to assess the overall burden on IRB members as well as address potential areas of weakness in the Human Subjects Protection Program in terms of resources.

Description of Program
A 40-item Likert scale anonymous on-line survey questionnaire with a center and neutral point that attempts to measure positive or negative experiences of IRB members in areas such as workload, meeting schedules, and satisfaction with resources was administered to all active IRB members. Data were collected over a 4-month period and analyzed using the most recent version of the Social Science Statistical Package (SPSS). Descriptive variables were analyzed and reported as proportions and frequencies. Eighty-seven IRB members were invited to complete the survey and 45 chose to do so (Response Rate = 53%). Approximately 46.5% of the respondents were physicians; 30.2% were other scientists; and 23.3% were non-scientists. Sixty-seven percent of the respondents had served on the IRB for less than a year to three years while 32.6% had 4 to 10 years of service. Fifty-five percent and 45% of the respondents were female and male, respectively. Seventy-two percent were affiliated with the institution and 27.3% were not affiliated. The survey revealed that a majority of the IRB members were satisfied with the quality of resources and the support that they receive from the IRB support staff. Eighty-three percent reported that their decisions and actions regarding human subject protection were based only on federal regulations, institutional policies, and practices rather than pressure from institutional officials. Approximately 92% of the respondents rated the following statement from “strongly agree” to “somewhat agree”: “I usually receive all the materials I need to conduct a thorough review of my assigned protocols.”

Evaluation Method: Results of the survey were presented at the annual IRB member retreat. Retreat participants included institutional officials and IRB administrators. The survey will be administered every three years to assess adequate functioning of the Human Subjects Protection Program or after significant turn-over in the IRB membership.

Suggestions And Next Steps: Based on positive feedback from members of the IRBs, OPRS has initiated a survey to be administered to members of the research community. The year-long data collection process will assess how the Human Subjects Protection Program is meeting the needs of researchers across the entire university.
IRB Pilot Evaluating an IRB Screening Tool to Differentiate Quality Improvement and Research
Authors: Stephanie Fotonoff, MHA, BS, CIP; Jeannine Brant, MSN, RN, PhD; Catherine Grott, MPA, PhD; Cindy Leenknecht, MS, APRN, BC, CCRP; Kyle Townsend, PharmD, BCPS

Background
Quality improvement (QI) clinical practice activities increasingly resemble research. No classification system exists to reliably differentiate QI clinical practice from research. Incorrectly classifying QI and research has significant adverse consequences. Current IRB communications with medical practitioners about activities that may be research consume time, energy, and patience due to complexity and ambiguity of human research protections. IRB of Billings investigators are developing a program and tools to distinguish between QI clinical practice and research.

Description of Program
IRB Protocol 09.14 This IRB “best practices” protocol improves local IRB services through a pilot feasibility trial to gather feedback from users of a written screening tool. If successful, this tool will increase the accuracy of classification by practitioners, researchers, and the IRB and may result in future research. Protocol will not assess instrument validity or reliability, and data analysis will be descriptive. Study duration is planned for approximately one year, for presentation of outcome results to PRIM&R. IRB of Billings approval was issued June 12, 2009, for IRB Protocol 09.14, with all investigators abstaining.

IRB Screening Tool Form was compiled and organized by IRB Administrator from published sources after extensive research into quality improvement and research. Decision criteria follow an IRB consultation process currently used for new study submission involving activities that resemble quality improvement and may or may not be research, as follows:

- Page 1: Project demographics; Tool evaluation self-report.
- Page 2: Quality improvement criteria, including 2009 federal guidance.
- Page 3: Research criteria, including federal definitions/guidance and published interpretations.
- Page 4: Human subjects criteria, when IRB review is required, etc.
- Page 5: References and recommended reading.

Evaluation and recommendations for the tool will be provided by IRB staff/members and by elective self-report of practitioners/researchers. Local study subject recruitment of healthcare professionals included presentation by IRB investigators, titled “QI or Research? Implications for IRB Review,” to Medical Grand Rounds on May 29, 2009, and distribution of IRB Screening Tool.
Lessons Learned From Community-Wide IRB Authorization Agreements

Authors: Tonya K. Edvalson, BS, CIP; Michael W. Varner, M.D.

Background
The Obstetrics and Gynecology Research Network is the research administration division of the Department of Obstetrics and Gynecology at the University of Utah Health Sciences Center and focuses on community-based NIH-funded women’s health clinical research. Regulatory requirements, engagement of research definitions, inexperience and local policies of community hospitals and private practitioners have presented challenges to the development and implementation of this process in community settings.

Description of Program
Two options are used to obtain appropriate IRB coverage for implementing IRB Authorization Agreements (IAAs): 1) Free-Standing IAA for private practice settings without an IRB; and 2) Collaborative IAA for hospitals that have an IRB. IAAs decrease administrative burdens for investigators, private offices, and community IRBs. It is apparent that obtaining an IAA is only the first step in a process that becomes more complex as implementation proceeds. Since March 2006, nine IAAs: 3 Collaborative IAAs and 6 Free-Standing IAAs have been executed. It has been a time-consuming process that bespeaks the importance of knowledge of regulations/policy, development and maintenance of trust, and understanding of community-wide concerns. Community hospitals with IRBs have been most likely to express concern about local oversight of a study once an IAA is signed.

To mitigate these concerns, we have applied the following processes.
- “Baby Steps,” applying IAAs to activities that are no more than minimal risk.
- Add staff and/or IRB member as contact for the study.
- Facility-specific consent documents.
- Credentialing University of Utah research staff, as required.
- Open and transparent communication.

Community practitioners are not primarily driven by research interests. Fully informing the practitioners of the process, we take great efforts to minimize the burdens placed on them in order to participate. We employ the same processes as described above, but are faced with the following challenges that are unique to this group:
- Determine engagement in research.
- Describe/monitor FWA and IAA process.
- HIPAA
- Training practitioner/staff members responsible for research-related activities.

Suggestions: Experience has taught us to consider the following before approaching a community-based practitioner or hospital for execution of an IAA.
- Ensure reviewing IRB is supportive of IAA.
- Have Frequently Asked Questions, Information Sheets, signature-ready forms, submit IAAs and FWAs for the entity.
- Emphasize importance of community-wide support of research.
- Understand community hospital and practitioner policies.
- Provide appropriate training to practitioner/staff to protect participants and ensure protocols are appropriately followed.
- Patience is critical.
Navigating the NIH Roadmap: Review of a Clinical Data Repository for Translational Research
Authors: Jeanne Velders, JD, RN, CNMT, Christy Auston, MA, & Philip Ludbrook, MD, FACC

Background
When a research project involves innovative technological and electronic applications, policies and guidance intended to protect human subjects but developed decades earlier may pose significant challenges for IRBs and investigators alike. In such cases, the regulatory requirements and ethical principles applied during IRB review may not provide clear direction through this seemingly unchartered territory.

Description of Program
At Washington University’s School of Medicine (WUSM) in St. Louis, a protocol developed by Clinical and Translational Science Award (CTSA) investigators proposed the creation of a comprehensive electronic data repository via duplication of retrospective and prospective clinical data from all available patient medical records at the Washington University Medical Center and its affiliate hospitals. From this main repository, the Clinical Information Data Exploration Repository (CIDER), clinical researchers will use a software interface to gain access to data for their individual research needs, following IRB review and approval of protocols when applicable. The intent is to develop a comprehensive electronic data “warehouse” to foster clinical and translational research, provide researchers with easier access to complex datasets, and speed the process of scientific discovery and the development of generalizable biomedical knowledge. While the project enacts the CTSA mission to minimize barriers to clinical and translational research as part of the “NIH Roadmap,” the review process was not easily navigated. We propose to discuss the review process, examining the major ethical, regulatory, and procedural issues involved, including the following:

- Does the mere creation of this data repository constitute research itself?
- Can a waiver of consent be justified for such research?
- Would the lack of an “opt-out” option compromise participants rights to autonomous decisions regarding their own protected health information?
- Would the inclusion of an “opt-out” option diminish the value of CIDER, by reducing the scientific integrity of the data repository and thereby degrading its utility?
- What level of data security is sufficient to protect confidentiality?
- What special protections are required for potentially sensitive data and vulnerable populations?
- Who should be responsible for organizational oversight of the project?
- Finally, are the DHHS regulations and the Belmont Report flexible enough to accommodate innovations spurred by the NIH Roadmap?

Additional ethical concerns will be discussed, as well as recommendations for IRB review of extraordinary research proposals that exemplify the competing tensions between the need to advance scientific research and the need to protect human subject populations.

Additional Information
The Principal Investigator of the project, Rakesh Nagarajan, MD, PhD, intends to submit an abstract presenting his perspectives on the IRB review process, ethical considerations, regulations, etc. We believe this project would make an interesting panel presentation, and Drs. Ludbrook and Nagarajan would be happy to participate in such. In addition, including an OHRP representative on such a panel would be extremely informative.
Nurturing the IRB-Investigator Relationship
Authors: Keren Patricia Dimah, MPA, MPH, CIP; Eileen Yates, CIP; Tasha Osafo, CIP; Debbie Gibson Tice, CCRC, CIP; Don Workman, PhD

Background
“HHS regulations at 45 CFR 46.109(d) requires that an IRB notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.” Investigators and IRB members should interact meaningfully and actively to facilitate the review process. Human Subjects Protection Programs that utilize the primary-reviewer process can effectively nurture positive relationships between IRB members and investigators. The intended outcome was to explore the possibility of building a collaborative partnership between IRB members and investigators during the review process. Specifically, we were interested in determining the level of contact that IRB members would be willing to make with their colleagues during the review process to resolve issues likely to delay approval of research.

Description of Research
A 40-item Likert scale anonymous on-line survey questionnaire with a center and neutral point to measure positive or negative experiences of IRB members in areas such as workload, meeting schedules, and interaction with members of the research community was administered to all active IRB members. Data were collected for a period of four months and analyzed using the most recent version of the Social Science Statistical Package (SPSS). Descriptive variables were analyzed and reported as proportions and frequencies. Eighty-seven IRB members were invited to complete the survey and 45 chose to do so (Response Rate = 53%). Approximately 46.5% of the respondents were physicians; 30.2% were other scientists; and 23.3% were non-scientists. Sixty-seven percent of the respondents had served on the IRB for less than a year to three years while 32.6% had 4 to 10 years of service. Fifty-five percent and 45% of the respondents were female and male, respectively. Seventy-two percent were affiliated with the institution and 27.3% were not affiliated. The findings revealed that approximately 50% of respondents were willing to initiate contact with investigators during the review process. On the other, 83% of the respondents reported that investigators and research coordinators are responsive when contacted about their IRB applications. This is a clear indication that investigators and IRB members can work together to resolve issues. Interestingly, 52.6% of respondents did not report any discomfort with contacting investigators that were from their respective departments.

Evaluation Method: IRB administrators have been trained to facilitate positive interaction between IRB members and investigators during the review process. Our electronic submission system has improved the rate at which IRB members and investigators interact during the review process. We have observed that compared to the paper system, it is more convenient for IRB members to initiate contact with investigators and research coordinators in the electronic system by simply logging a comment. Previously, the only way that communication was possible was via email or telephone.

Suggestions And Next Steps: We will revisit this issue by conducting another short survey after full implementation of our electronic submission system in 2010.
Post Approval Monitoring of the Informed Consent: 45CFR46.116(a)(7)
Authors: Eileen M. Yates, BA, CIP; Olga Kwiecien, BA; Jonathon Goldman, MD, MS; Robert McCarthy, Pharm.D.

Background
Institutions with sufficient resources and a commitment to excellence in human subject protections are exercising the role of post approval monitoring. Though Investigators are required to provide contact information in the consent document, the telephone number provided often goes unchecked by the IRB, in spite of its role as an important aid for research participants.

The intended outcome is to verify the accuracy of the information provided in the consent, which includes whether research personnel are appropriately fielding these calls, and the availability of the Investigator. As the results of the activity are measured, key issues will be identified in order to develop educational activities for the research community.

Description of Program
5% of the active research projects are evaluated each year. In order to ensure accurate management and follow-up of findings, ~1.3% will be audited each quarter. The quality assurance activity includes:
- Pull a random sample of current consent documents from active projects enrolling subjects. Make a copy of the consent document(s).
- Pull the current research personnel list.
- Call the phone number listed on the consent document and record the following information:
  i. Who answers?
  ii. Are they the research personnel?
  iii. If voicemail is reached, when is the call returned?

The results of the activity included follow-up with the Investigator requesting that a revision in order to bring the study into compliance. Twelve of the 38 telephone numbers provided at the initial contact reached a voicemail. The study staff or the Principal Investigator returned about 67% of these calls within 24 hours. As a result, a consent training session has been developed for the research community.

Evaluation Method: The IRB Chairmen and Institutional Officials evaluate the results from this activity. The results will aid the future development of educational programs available to the NU research community.

Suggestions and Next Steps: Each research program has unique needs and the resources available to them will need to be evaluated in order to assess adding this post approval monitoring to their program. It has been our experience that this relatively small number of projects is not only manageable, but has yielded beneficial results, including Investigator feedback.
Pregnancy Testing Policy
Authors: N. Jean Amoura; Toby Schonfeld; Joseph S. Brown; Bruce Gordon

Background
Many protocols exclude pregnant women in clinical trials. One mechanism for ensuring that women of childbearing potential are not pregnant is by requiring contraception. We designed and implemented a Contraception Policy to standardize contraceptive requirements and consent form language for studies involving contraception; our work on this issue has been published in IRB (Schonfeld and Gordon, 27.2 (2005): 15-20) and in The Journal of Women's Health (Schonfeld et al., 18.4 (2009): 507-512). In addition to required contraception, many protocols also require pregnancy testing as a means to identify pregnant women to minimize risks to the fetus or minimize variability associated with the pregnant state. In an effort to standardize pregnancy testing procedures, and to correlate these procedures with actual data about risk, we devised and implemented a Pregnancy Testing Policy for studies involving women of childbearing potential.

Description of Program
Based on our observations that protocols were inconsistent with regard to type of pregnancy testing, frequency of testing, payment source for testing, and the relation of testing to contraceptive requirements, the IRB decided that standardization of procedures and consent form language was warranted. The IRB Pregnancy Testing Subcommittee designed a policy that prescribed the appropriate methods, frequency, and notification procedures that should be followed when risk to a potential fetus is a concern on a research study. The Pregnancy Testing Policy includes the following:

- Definition of women of child-bearing potential;
- Circumstances when self-report of pregnancy status is adequate, specifically when there is no expected risk to a fetus;
- Whether a clinical test, as opposed to self-report, is indicated;
- The type of clinical test indicated;
- When the test needs to be performed and whether it should be repeated, and if so how often;
- Who will pay for the pregnancy test;
- How the results will be disclosed to the subject; and,
- Required information in the consent form addressing notification of minors and their parents, as well as procedures if a subject becomes pregnant during the study.

Suggestions for future use at home institution: To assess the value of this policy, we are undertaking several studies. Concurrent with the submission of this abstract, we are reviewing clinical trial protocols involving women of child-bearing potential submitted to the IRB before the policy implementation. Protocols will be assessed according to whether or not the study excluded pregnant women, whether the study required contraception, whether or not pregnancy testing was required, and the methods and frequency of the pregnancy testing. In addition, we will maintain a database that includes the characteristics of protocol changes regarding pregnancy testing required for protocols to be compliant with the new policy. We will also evaluate the frequency and type of requests for exception.

Suggestions for implementation at other sites: Institutions that are not regularly monitoring pregnancy testing requirements should consider providing guidance through policy development that ensures standardization of pregnancy testing procedures and consent form language.
Promoting Communication Within a Centralized Office of Research Administration
Authors: Jessica Conrad, MS, CIP; Jennifer Oettinger, RN, JD

Background
Summa Health System is currently evolving from a community hospital into a community-based academic medical center. Attendant with that evolution is a significant growth in the research enterprise across the institution. In order to support that growth adequately Summa has created a centralized Office of Research Administration. As we organized our centralized research administration office at Summa we planned for the need to establish best practices to ensure consistency between research informed consent forms, the contract, and all of the regulations and accreditation standards.

Description of Program
The following best practices were established:
- Establishment of a checklist for consent forms which includes the eight federally required elements.
- Establishment of a checklist for review of contracts that includes the elements in Domain IV of AAHRPP accreditation recommendations and comparison of consent form and contract.
- Establishment of a contract template that includes the elements in Domain IV of AAHRPP accreditation recommendations.
- Research Grants and Contracts Director attends the IRB committee meetings to provide clarification when necessary and to identify any liability or safety issues the committee is not aware of.
- As needed the Research Grants and Contracts Director and the IRB Manager review and discuss the informed consent document as well as appropriate contract language to ensure appropriate human subject protection.

A Quality Assurance program was established where 10% of all contracts are reviewed by the audit team to ensure that all of the elements in Domain IV were addressed. The contract is compared to the consent form to ensure consistency. The consistency between contracts and consent forms is essential to maintain human subject protection and these best practices will continue at Summa as we continue to grow the research enterprise. The templates and checklists that were created for this process will continue to be reviewed on a periodic basis to ensure that they are still correct in regards to current data. It is critical to create templates with appropriate language and a checklist can be very useful. Even with templates and checklists, there must be an open avenue of communication between the IRB and Research Grants and Contracts offices.
Background
Investigators and research staff may perceive the IRB as a roadblock or a hurdle on the path to initiating new research. The IRB approval process can be time-consuming, confusing, redundant, and highly detail-oriented, and researchers may not always see the connection between IRB approval and protection of human subjects. The key to improving IRB processes is to understand the local research community’s expectations and needs. While providing ongoing education is an important component of any QA/QI program, the progressive IRB should consider implementing tools to capture significant data on an ongoing basis from the community they serve. Engaging the research community in providing regular feedback on IRB services and processes—in the form of customer satisfaction surveys, open forums, user groups, etc.—will not only establish reliable sources of data on which to launch new initiatives and measure progress, but will also serve to build and enhance the relationship with the research community over time.

Description of Program
The Quality Improvement Program at Cedars-Sinai Medical Center’s (CSMC) Office of Research Compliance and Quality Improvement (ORC&QI) comprises multiple approaches to assess the IRB’s strengths and weaknesses, and to use the resulting data to implement new efforts in rapid response to feedback received. These approaches include multiple surveys targeting IRB users, quarterly and annual tracking and reporting of turnaround statistics, a robust post-approval auditing and monitoring program, an ever-evolving educational outreach program, as well as a tireless quest for self-improvement that is championed by the Director of the ORC&QI and fostered by the institutional culture. The focus of this presentation is on how one specific initiative—the annual IRB Review Process Survey (henceforth referred to as “the annual survey”)—when analyzed in combination with annual turnaround statistics, has provided the foundation for significant, timely process improvements in the services offered by the CSMC IRB.

In January 2009, members of the CSMC research community participated in the fifth annual survey to gather feedback on their experiences working with the IRB during 2008. The survey included several questions intended to gain a better understanding of the makeup of the research community, such as the respondent’s role on their research study, the type of research they are involved with, how often they are involved with IRB submissions, and their comfort level with using the internet and e-mail. A number of questions attempted to gauge their experiences with navigating the Webridge online protocol submission and tracking system, and their thoughts on the amount of time required for IRB review of their submissions. Additional questions attempted to gauge their thoughts on the quality of IRB review at CSMC, the feedback sent by IRB staff on their submissions, and their perspective on the role of IRB review in facilitating research and the protection of human subjects populations responding to the original and follow-up surveys were relatively similar with respect to reported role in research at CSMC, departmental affiliation, and reported comfort level with computers.

While responses to the 2008 survey showed some setbacks in certain areas, overall satisfaction remained high. A summary of the feedback received from the research community follows:

- In general, the research community appreciates the exceptional service provided by ORC&QI staff and feels the IRB review process at CSMC has improved significantly over the years.
- Additional enhancements are needed to the user interface for Webridge, the on-line IRB submission, tracking and review system, such as renaming buttons and links, to make it more intuitive and user friendly, and to allow for easier access to study documents.
• Improvements to the Study Application are necessary to eliminate redundancy, allow for greater flexibility in answering questions, make wording more clear in certain areas, and to avoid unrelated questions by better tailoring applications to different types of studies (such as case report exemptions).

• The research community is interested in seeing a reduction in the time-lag between IRB Review and final study approval (relating to reviews by ancillary committees after IRB approval, such as the Medical Radiation Safety Committee or finalization of the contract).

• There is a need to expand and better advertise educational opportunities, such as IRB Office Hours, Grand Rounds, and workshops.

The feedback received during the annual survey is often the most straightforward, poignant communication we have with the research community. Regardless of whether it is positive or constructive, the research community relies on the ORC&QI survey results to provide benchmark data. Over the 5 years since the annual survey was first implemented, the data has consistently reflected the changes the CSMC IRB made to keep pace with an evolving research environment. These changes have so far included the implementation of and multiple revisions to the Webridge system that has been used at CSMC since 2004; the systemization of required IRB Analyst pre-review and a rolling deadline for new submissions; the development of educational outreach efforts such as IRB Office Hours; the overhaul of CSMC consent form templates to make them much shorter and more comprehensible to potential research participants; and the address of issues pertaining to ancillary committee review. All of these improvements have justified and been accompanied by an expanding staff to meet demands for decreased turnaround time and new programmatic endeavors.

The annual survey is conducted anonymously online, and the results can be unexpected. For instance, while the 2008 annual turnaround statistics consistently demonstrated dramatic improvements in IRB approval turnaround time, PI satisfaction with turnaround time actually decreased when compared to the previous years’ survey results. This presents challenges and opportunities for fine-tuning IRB processes to enhance the customer experience.

Suggestions for future program usage at home: Although the annual survey has given the ORC&QI extremely valuable feedback to support QI initiatives, it has some limitations. First, since the survey is anonymous, it can be difficult to understand the context of some of the comments received. Second, since the survey is administered annually, it is not always the best way to evaluate programs and improvements implemented throughout the year. Therefore, we recently launched a post-approval survey that is sent to the specific research team after each new protocol is approved. This survey is not conducted anonymously, in order to capture more specific feedback from research teams about further improvements we can make in the IRB review process. We also hope that this survey will help us to identify specific types of studies where QI efforts should be focused.

Suggestions for implementation at other sites: The CSMC ORC&QI has adopted a Code of Communications that represents our commitment to listen, share, learn and improve. We practice that code within the office and with the research community. The costs associated with these initiatives are relatively low, and the pay-off is potentially tremendous. With an annual subscription to an on-line survey tool, any organization can start to develop these assessments. Using the on-line survey tool or software that most organizations already own, such as Microsoft Excel and Access, the resulting data can be converted into meaningful graphics to generate conversations and ideas for improvement. Through trial and error, these simple tools can lead to great leaps in continuous quality improvement.

Additional Information
“Turnaround” is defined as the time between submission and approval of a new study, amendment, continuation, or any other type of submission subject to IRB review and approval or acknowledgment. The cost for a non-profit subscription to on-line survey tools is generally <$500/year.
Protecting Human Subjects Participating in Mental Health Research Via Ongoing Consent Monitoring

Authors: Carol J. Squires; Katherine J. Whorton; Mary Ellen Cadman; Julie Brintnall; Maria Rita Vieira; Maryland Pao; Barbara Karp

Background
The National Institute of Mental Health (NIMH) Office of the Clinical Director established the Human Subjects Protection Unit (HSPU) in July 1999. This multidisciplinary team, independent of the researchers, was formed to provide potentially vulnerable subjects with multiple levels of protection during participation in clinical trials.

Description of Program
The HSPU is comprised of Masters’ level social workers and nurses with specific clinical and research ethics training and experience in the assessment and monitoring of subjects participating in mental health studies. HSPU ensures human subjects protection through:

- Consent & Assent Monitoring;
- Capacity Assessment;
- Assessment of Surrogate Understanding;
- Assessment of Subject’s Ability to Appoint a Research Durable Power of Attorney (DPA);
- Ongoing consent monitoring during study participation;
- Consultation to IRBs;
- Protocol pre-review of human subjects’ protection plan; and
- Education of subjects, investigators and staff on human subjects’ protections issues.

This poster focuses on an aspect of human subjects’ protections which is unique to our group: the ongoing consent monitoring of mental health participants in an inpatient research setting. NIMH intramural studies currently include adults and children with mood or psychotic disorders. HSPU monitoring includes:

- The assignment of an HSPU Clinical Research Advocate (CRA) to every inpatient participant to monitor ongoing capacity and consent/assent;
- Formulation of a subject- and study-specific monitoring plan;
- Participation in interdisciplinary team meetings and direct communication with investigators; and
- Written documentation.

Ensuring monitoring plans and the results of monitoring are reported to the IRB Program Evaluation Program review and evaluation are conducted annually, including:

- Number and nature of protocols and number of subjects monitored;
- Results of consent monitoring, capacity assessments and surrogate assessments;
- Feedback from IRB, investigators and subjects, including requests and requirements for further HSPU involvement;
- Use of HSPU services by other NIH Institutes future use continued collaboration with other departments involved in human subject protections such as Bioethics, IRBs, medicolegal, etc.;
- Identifying and developing new human subjects’ protection policies and guidelines, for example, how to conduct research with adults who have never had capacity to provide informed consent or to appoint a research DPA Further development of educational programs.

Suggestions for implementation at other sites: Our best practices can be adapted to other research venues. Small programs may not require full-time HSPU staff. Costs can be minimized and resource allocation maximized by training and assigning existing staff to perform human subjects’ protection functions.
Protocol And Consent Form Amendments: A Look At The Submission And Review Process
Authors: Roy Cambria; Bonnie Edelman; Margaret Isaacs; Jane Myers; Joseph Lengfellner; Roger Wilson, MD; Collette Houston

Background
In 2008, the Institutional Review Board/Privacy Board Office staff and the Clinical Research Quality Assurance Division in the Office of Clinical Research (OCR) at Memorial Sloan-Kettering Cancer Center (MSKCC) conducted a comprehensive audit on the Institutional Review Board/Privacy Board (IRB/PB) amendment submission and review process. Protocols had been amended via a memorandum written by the Principal Investigator and accompanied by updated protocol documents. Amendments were reviewed at a full Board meeting held every two weeks. In 2008, an average of 45 amendments was reviewed at each meeting. The overall goal of the audit was to ensure that all amendment changes were accurately reflected in the protocol documents (e.g., protocol, consent, appendices), and to identify areas where improvement to existing processes and procedures was necessary. The scope of the audit included 100 protocols amended between 10/1/07-3/31/08; this included the review of 184 protocol amendments and 134 consents.

Description of Program
The outcome of the amendment review yielded positive results: in 100% of the amendments reviewed, all toxicity and/safety information updated in the protocol was appropriately updated in the consent form, and 80% of the 100 studies found no patient safety issues. In 6% of the reviewed studies we did find major issues that could possibly impact patient safety. These were addressed with the Principal Investigator at the time of the audit. The audit also highlighted areas that needed improvement and several steps have been taken to accomplish this: 1) implementation of a thorough QA of all currently approved protocol documents posted to the institutional protocol website, 2) revision of the reviewer Amendment Checklist, 3) re-education of the IRB/PB members to ensure proper amendment review, 4) institution of an electronic rolling submission of amendments and capping their number per meeting, 5) creation of an Amendment Submission Form and updated protocol/consent templates, 6) establishment of a dedicated email amendment account, and 7) expedited review for investigator/consenting professional changes only.

The audit results provided feedback and guidance to the institutional research staff about the problems that can be avoided prior to the amendment submission process. It also pointed out the need for restructuring the IRB/PB office. In this poster presentation, we will outline the methods on how we conducted the audit, the outcome, and the processes we revised to improve the overall amendment submission and IRB/PB review.
PTMS: A Custom, Electronic Platform for Improving IRB Processes

**Author:** Jennifer Morris; Marjorie Gillespie; Michael Chapple; Alex Noury; Maryland Pao; Jeanne Radcliffe; Maria Rita Vieira; Yang Fann; Gladys Wang; Barbara Karp

**Background**
IRB administration requires the ability to manage multiple concurrent processes. We developed the NINDS Protocol Tracking and Management System (PTMS) to facilitate protocol review administration. This secure, web-based system enables investigators to initiate, track, and organize clinical studies, monitor progress through the review process, view status changes, and quickly respond to requests for information. It allows the IRB staff to centrally track and manage the review and approval processes, including statistical, scientific, DSMB, and conflict-of-interest reviews. PTMS is fully automated and meets the NIST security accreditation standards.

**Description of Program**
Features that distinguish PTMS from other commercial or open source software are:

- **Remote Access Capability:** Around-the-clock access from any computer with an internet connection via a secure website.
- **Multiple Review Types:** Management of Initial Reviews, Continuing Reviews, Terminations, Amendments, Serious Adverse Events, Protocol Violations, and “Other Actions.”
- **Concurrent Reviews:** Support for multiple concurrent reviews for a single protocol.
- **Role Access Control:** Role-based access for different users.
- **Automated Notifications:** Automatic PTMS-generated e-mail notices to investigators, reviewers and IRB staff.
- **Reports:** The ability to export data into Excel, PDF and HTML formats for easy auditing and analysis.
- **E-signatures:** The ability to electronically sign, eliminating the need for paper and for transferring documents among signatories. Proxy signatures can be assigned.
- **Audits:** Recording of all entries into the system and all changes throughout the life cycle of each protocol.
- **Flexibility:** Ability to rapidly accommodate changes in the IRB review/approval process.

Regular upgrades incorporate new features requested by users. PTMS was developed by the NIH Center for Information Technology and the National Institute of Neurological Disorders and Stroke Information Technology team in collaboration with IRB staff. It is maintained on secure servers and backed-up daily. The system currently manages nearly 500 protocols from the 6 Institutes that comprise the Combined Neuroscience IRB. Suggestions for Implementation: PTMS has accelerated IRB processes, minimized errors and lost documents, and has been a major asset to all users. Proof of its success is that PTMS is being adopted by six other NIH Institutes.

**Additional Information**
Additional information at: http://intra.ninds.nih.gov/ptms.asp
Authors: Okoye Ol; Umeh Re

Background
Inherent limitations, constraints and challenges which would confront the sponsor IRB in reviewing international research protocols, with respect to Nigeria. The intended outcome is a better contextual appreciation of what it takes to conduct an ethical research in Nigeria.

Description of Program
The institutional review boards or health research ethics committees are charged with a mandate to approve or withhold approval for proposed health research based on ethical and scientific considerations. This is critical to the preservation of individual and public trust in the research enterprise. In a paper published in IRB: Ethics and Human Research (25 number 2, 2003) titled “Ten questions Institutional Review boards should ask when reviewing international clinical research protocols”, Fitzgerald DW along with Wasunna A and Pape JW, posed 10 crucial questions which would enable IRBs of wealthy sponsor countries to conduct more thorough review of international clinical research protocols. Drawing from our experiences as local researchers in Nigeria and from contributions on the floor of a bioethics class meeting, we have made attempts to explore those limitations, constraints and challenges which would ordinarily confront the sponsor IRB in trying to provide logical, conclusive answers to the 10 posers. With scanty references to the controversial Pfizer Kano Trovan study, we re-emphasise in this presentation the dire need for an adequate understanding of the socio-cultural and politico-economic conditions prevailing in the proposed host research community. A consideration that is presumably often under-estimated is that research is not yet a top priority in Nigeria (lack of demand for and social appreciation for research) coupled with the fact that there is a paucity of policy-driven quest and appropriate incentives to create the enablement and zeal for ethical research. The appraisal of these 10 questions suggests that the most daunting challenges will be in the areas of the independent review/monitoring process, the informed consent process, maintaining a favourable risk-benefit ratio during/after research and ensuring collaborative partnerships with competent researchers with integrity.

Suggestions, such as determining whether the local collaborating partner has a good measure of intellectual independence or strong ethics tradition, are thus made which may prove beneficial in the review of future international health research protocols.

Additional Information
I acknowledge the contributions of my classmates and teachers in the Msc bioethics class.
Rapid Cycle Improvement of Expedited Review at the IRB
Authors: Jim Pringnitz; Rita Basu, MD; Carol Siegel; Ben Wibstad; Muhanad Hirzallah; Marcia Andresen-Reid; William Tremaine, MD

Background
The IRB electronic system design was inefficient in facilitating review of minimal risk applications. The shortcomings in the system design negatively impacted the time required to process minimal risk applications. The goal of this project was to improve the IRB operational model and electronic processing of minimal risk applications, continuing reviews and modifications to research. Success looks like:

- streamlined procedures and documentation methods;
- efficient model for processing items in IRBe;
- a process that meets regulatory requirements and AAHRPP standards; and
- more efficient use of resources.

Description of Program
The PDSA cycle is a continuous quality improvement model consisting of a sequence of four steps for improvement and learning. The approach aids in testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act). The PDSA cycle was used iteratively to accomplish the following results:

- Design of a new workflow in IRBe with a >50% reduction in click rate.
- Replacement of agenda processing with a one piece flow process.
- Standardized notifications and a reduction of templates.
- Work instructions for orientation and training.
- Development of a reporting tool for future PDSA cycles.

The PDSA cycle is a ‘back to basics’ approach to continuous process improvement. It originated in the 1920s with Walter Shewhart’s Plan, Do and See model. W. Edwards Deming modified the cycle towards the current Plan-Do-Study-Act. The model is widely documented and applies to any problem or opportunity.
Reduction of Rework for IRB Submissions – a DMAIC Project
Authors: Michelle Daiss; Jim Pringnitz; Mindy Rice; Helen O’Connor; Angie Patterson-LaBaw; Tammy Dull; Karen Hurtis

Background
The Mayo Clinic Institutional Review Board (IRB) utilizes a screening process to assess the completeness and accuracy of submissions in preparation for expedited or fully convened IRB review. Approximately 50 percent of submissions are returned to the research team for changes prior to formal review. The resulting rework adversely influences resource utilization, overall turnaround time, customer and employee satisfaction, and, ultimately, human subject protections.

Description of Program
This project focused on identification and elimination of the most common reasons for change requests associated with new research applications, modification requests, and continuing review/final reports. A six-month timeline was established with an end goal of achieving and sustaining an 80 percent reduction in rework by researcher teams and IRB personnel. After training in process improvement tools and techniques, the project team completed each phase of the DMAIC process in sequence. DMAIC is a structured problem-solving method consisting of five phases – Define, Measure, Analyze, Improve, and Control. The analysis of more than 800 change requests issued over a one-month period revealed the top 10 common issues accounting for 80 percent of the rework. Root cause analyses were completed within each of the ten issue categories. Several straightforward administrative and technical remedies could be implemented without delay.

For the more complex issues or those having diversity of origin, the project team partnered with representatives of the Mayo Clinic research community to solicit first-hand, customer perspective and expertise. On-line, collaborative brainstorming using Launchpad software (Imaginatik) and usability testing were among the techniques employed to capture the voice of the customer and to conduct small tests of proposed solutions.

Preliminary data demonstrate an initial 43 percent reduction in change requests associated with continuing review/final report submissions. The project is ongoing with continued progress, evaluations and results to be summarized.
Research Based Radiation Procedures: A Comprehensive, Parallel Review Process
Authors: David A. Hiller, RN, BSN, CIP; James Arrington, BA, CIP

Background
The number of radiological procedures, such as x-rays, CT scans, PET scans, etc..., used in research is increasing each year. Does the increase in the use of radiation based procedures increase the risk to participants? What is appropriate with regards to the depth of review for these procedures in the context of the study review? These questions are becoming more relevant as exposure to radiation through participation in research becomes the norm. In looking at the review process for radiological procedures in research at different institutions nationally, the modality of review varies, with some delegating the review responsibilities outside the IRB to a Radiation Safety Committee, or a Radiation Safety Officer, or including the radiation review within the overall review of the study by the IRB.

Description of Program
At Vanderbilt University Medical Center, all radiation exposure that is related to research participation is reviewed in a comprehensive manner based on the level, or amount, of exposure and takes into account vulnerable populations such as children, pregnant women, or healthy volunteers. The review is performed by a separate committee within the IRB which specializes in radiation procedures and dosimetry. The Human Subjects Radiation Committee (HSRC) acts in a dual role, as it serves as the Radioactive Drug Research Committee (RDRC) for research using radio nuclides.

The specialties of the RDRC are mandated by the FDA and include a physician specializing in nuclear medicine, a dosimetrist and a nuclear pharmacist, at minimum. Vanderbilt’s HSRC/RDRC consists of a nuclear physician, two dosimetrists, a nuclear pharmacist and a radio-oncologist. A Radiation Safety Officer from the institution also serves as an ex-officio to the Committee. The radiation review process parallels the human subjects review and allows collaboration between the Radiation Committee and the Health Science Committee, providing an in-depth review with the protection of human subjects as a primary focus. Adherence to State and Federal laws is also a consideration. As the risks associated with exposure to radiation are thoroughly reviewed and discussed, appropriate risk language is developed to aid the research participant in understanding some of the risks of participation.

The intended outcome of this type of radiation review process is to ensure that research participants are aware of any exposure to radiation received as part of participation in research, and the risks associated with that exposure. This helps to enable prospective participants to make a truly informed decision about taking part in the study. The radiation review process is evaluated through analysis of time measures to make sure the separate review process does not substantially hold up the review of the entire study. Allowing the reviews to be done in parallel helps limit any extension of overall review time.

The development of an HSRC at any institution would greatly depend on the amount of research studies utilizing radiological procedures for the purpose of collecting research data. If an RDRC already exists, this would be an easier task. As research studies rely on more radiological procedures to obtain data, and as new technology brings forward more radiological procedures to be tested and approved, the need for a detailed review of those procedures is becoming clear.
Research On IRB Processes: A Methodological Study Describing The Evaluation Of Two Central Irbs
Authors: Christine Murray; Cherisse Harden; Nicole Flores; Todd Wagner, PhD

Background
In recent years, there has been a growing interest in how human research protection programs (HRPPs) operate and how they protect human subjects. Following highly publicized human subjects problems in the 1990s, debates arose over quality, conflicts of interest, resources and process of consent. The field has embraced some changes, such as accreditation, yet there have been little data to suggest that these changes have been beneficial. Studying HRPPs is challenging because no standardized data exist. For the past four years, we have been studying the NCI and VA central IRBs. This paper describes our methodological approaches, the barriers we have encountered, and our solutions for overcoming these barriers.

Description of Research
Methods: At the onset of the NCI Central IRB Evaluation, we developed surveys to gather information from investigators and IRB personnel regarding their time and effort on IRB reviews. During the pilot phase, we learned that recall posed a problem. To counteract this, we modified our approach and surveyed participants about their most recently approved IRB action instead of a specific protocol. The development of the VA Central IRB Evaluation afforded us the opportunity to improve our survey methods. In this longitudinal study, we survey research staff for multi-site studies from the time of initial IRB submission to continuing review approval. We emailed researchers monthly asking about IRB related work. Each time a participant’s IRB submission is approved, our plan was to send them a survey, which asks more detailed questions regarding their work on this action, and then survey the IRB.

Results: In our NCI Central IRB Evaluation, we had a 60% response rate from research staff and a 40% response rate among IRB staff. The VA central IRB Evaluation has built on the NCI study and has been able to collect data soon after an IRB action happens and track several IRB actions within one study. However, we have encountered other problems; attrition among researchers has been higher than expected and many researchers use terminology that is site specific. Our biggest obstacle, however, remains the challenges of collecting data from IRB staff. Out of the 20 possible IRB contacts to survey for the VA IRB Evaluation, 8 agreed to participate. Of these, five actually completed the survey, leaving us with a response rate of 25%. Based on this, we are modifying our IRB survey from being administered to specific IRB staff following their approvals, to a more general sample, in which we ask more universal questions regarding IRB work.

Conclusion: Investigating research staff’s IRB related work is feasible. More challenging is studying processes within IRBs. Studying these processes may require the development of standardized data that can be extracted from protocol tracking systems.

Additional Information
This is a comparative methods analysis of two different ways to research IRBs. It may therefore differ somewhat from other scientific proposal abstracts.
“Response To IRB Conditions” - A New Way To Accelerate The Process Following A Full Board Meeting

Author: Sharon Zack

Background
Researchers typically working with tight deadlines and deliverables are eager to proceed with their studies when their projects are reviewed by a convened IRB. Per 45 CFR 46 111 (d), it is the IRB’s responsibility to communicate to the researchers promptly in writing of its decision to approve, require changes or disapprove a study. However, countless hours may pass before the minutes are recorded and a letter is sent to the Principal Investigator describing the IRB’s determination and, when necessary, a list of conditions to address prior to conducting research with human subjects.

Description of Program
After a thorough review of the current procedures, interviews with investigators, IRB members and staff, the following points were confirmed: 1) researchers request a quick turnaround on conditions imposed on their projects, 2) waiting for more formalized letters to be received can cost delays in moving forward on a researcher’s project, 3) researchers appreciate a list of the conditions and clear instructions of the procedures required to identify their responses as well as the location (page number) where the responses can be found in their original application. The end result was the development of a new form titled “Response to Conditions” designed in a table format and divided into the following sections:

1. Instruments/Procedures
2. Informed consent
3. Data Security/data destruction
4. Data analysis
5. Prime/subcontractor
6. Continuing review less than 12 months
7. Other

Researchers receive the “Response to Conditions Form” quickly, usually within one day, including a detailed list of conditions imposed by the IRB Board and instructions on completing and returning the form to the IRB. Once the researcher responds and identifies the page numbers where the changes can be found in the original IRB application, this form, and its supplementary materials (which clearly indicate the change made in response to each condition listed) are resubmitted to the IRB.

The feedback thus far about the use of the form has been quite favorable. When reviewed, an IRB can clearly see how and where the modifications have been made to the resubmission. Other human subjects’ protection programs may find this type of form user-friendly, helpful to the IRB, its staff, and the researchers, in order to provide detailed and well-organized written conditions in a timely fashion.
Revitalizing the Human Subjects Protection Program at a Small Independent Specialized Health Care Education Institution

Author: Patricia M. Cisarik, OD, PhD

Background
The conduct of original research at a small, independent health care education institution whose primary mission is teaching was stymied by misunderstanding and confusion about the review process required for studies involving human subjects. Though most of the protocols would qualify for IRB exemption or for expedited review, the process was considered by many too cumbersome. To demonstrate support for research initiative, a revitalization of the Human Subjects Protection Program was instituted, with the specific goals of 1) making the application for the initial review of a protocol more transparent, and 2) streamlining the approval process as much as possible.

Description of Program
The IRB Chair prepared policy documents that were more accessible to faculty members using Microsoft WORD with links between documents, to minimize repetition, and to the Office of Human Research Protections, so that the viewer could access the federal regulations mandating the establishment of the policies. These documents were then placed on the college’s internal website (Microsoft Sharepoint), from which, after log-in, they can be accessed at any time. Additionally, the applications for Exemption from IRB Review and for Initial IRB Review (expedited and full) were re-designed in fill-able pdf format to facilitate their completion. Templates also were provided for documentation of informed consent. The documents required for each type of application were placed in Sharepoint folders labeled according to the type of application materials contained. Reviewer documents were also made accessible so that investigators would know the factors considered in a review. Finally, a one-hour “Human Subjects Research Update” education course was presented to the convened faculty to provide clarity on the federal regulations and to demonstrate the ease of access to the documentation required for review of protocols involving human subjects.

The IRB has been able to complete the same number of reviews in the nine months since the program began as in the 12 months prior to the re-organization of the Human Subjects Protection Program, with exempt and expedited reviews completed within a week of submission. Additionally, faculty response has been positive, with at least one member submitting a protocol who had not done original research in more than 5 years. The more-structured framework for the full-review process was completed in time to consider the protocol for a FDA drug study, with the review being completed within 2 weeks of receipt of all review materials. Future modifications of the program include converting the pdf forms to Microsoft InfoPath documents so that proprietary pdf development software is not required for faculty members to save electronic versions of the IRB forms in order to edit them as requested during the IRB review process. Use of InfoPath documents will also permit electronic signatures and for searching documents.
Saving the IRB Coordinator’s Time by Activity-Based Cost Accounting
Authors: Donna Peters, CIP; Rosemary Cogan, PhD, ABPP, CIP

Background
Offices or entities that handle human subjects research all face a critical component: limited time. We carried out a cost analysis of part of the work of our IRB Coordinator to understand how to better manage an increasing work load.

Description of Program
We used an activity-based cost accounting approach (Michel, 2004) to understand the operational activities of the Institutional Review Board Coordinator. We used the results of the cost analysis to make a recommendation about a change in our operations.

Analysis of the Work of the IRB Coordinator: The IRB Coordinator (DP) identified 14 activities that are part of her job, including six activities associated directly with handling proposals such as: logging proposals, prescreening, first scanning, forwarding reviews to reviewers, processing approvals, and a second scanning. The IRB Coordinator monitored the time involved in each activity over a period of four days and determined the cost of each activity in time and salary. With an activity-based cost accounting approach, high-cost activities are first considered to see if they are high-value. An hour a week staff meeting, for instance, is high value. We calculated that handling a proposal required 54 minutes, of which 16 was for prescreening, a high-value activity. The average time for the low-value activities necessary for handling a proposal was 38 minutes. We calculated that aside from prescreening, with an on-line system, processing the low-value activities could possibly be reduced from 38 to 22 minutes.

Our office manages approximately 1,300 protocols a year at this time. We estimate that moving to an online system could lead to a savings of about 347 hours a year (1,300 x 16), or about one day a week. With this information, we will recommend that our university move to an on-line system.

Additional Information
An activity-based cost accounting approach has helped us understand the work of our IRB office and prepare a reasoned recommendation to university administrators. We recommend using this cost analysis approach as a way of looking at time management. We then can use the cost analysis to determine the ways of carrying out low-value activities by reassigning, removing or revising.
Situational Analysis of Botswana National Health Research Ethics Committee: A Strategy to Strengthen Capacity
Author: Mary Kasule

Background
Botswana is a semi-arid landlocked sub-Saharan country with an estimated population of 1.7 million people. The country has a stable democracy and an impressive record of sustained high economic growth thus considered a middle-income country with a GDP of US$ 12,387 (UNDP, 2007. The Botswana National Ethics Committee established in 1984 regulates all health and health-related research activities in Botswana. During the initial 10 years of its inception, the committee was mainly concentrating on development of health systems research capacity and was reviewing mainly biomedical protocols which posed minimal or no risk to research participants. Therefore not much attention was paid to the development and strengthening of a legal and ethical framework to protect the research participants. However, during the past decade, the advent of the HIV pandemic and the resurgence of communicable diseases particularly tuberculosis resulted in a shift of functions. Botswana’s HIV prevalence rate has for several years remained one of the highest in the world with an estimated 37.3% prevalence rate among pregnant women and 17.1% in the general population. Therefore, the committee is experiencing an increase in volume and complexity of research protocols submitted for review both national and international ones, especially Clinical Trials which require to be reviewed by members with a clinical/scientific and research ethics background.

Statement of the problem: Just like in many other developing countries, the challenge at hand in Botswana is the growing number of concerns about the inadequacy in the health research regulatory framework to protect research participants and the capacity of the committee to handle the large numbers of national and international multi-center research proposals submitted for review effectively and efficiently. Therefore there is an urgent need to strengthen the HRDC and HRU capacity in the above areas through reconstitution of the committee and continued training to avoid potential violation of the rights of research participants particularly in vulnerable communities.

Description of Program
Methodology: An internal desk review of the relevant working documents was conducted. Additionally, observation of the routine functioning of the HRDC and HRD were made to assess the adequacy of the National Ethics Committee governance system in order to come up with a strategy to strengthen the capacity of the committee.

Results: Results showed that the system currently lacks critical guiding documents. In addition other critical areas of concern identified were; the high turnover of both HRDC and HRU staff; lack of continuing education; inadequate financial resources; lack of provision of compensation to members for their voluntary work; lack of a feedback dissemination system to the research participants and host communities; and lack of guidance regarding sharing of benefits originating from potential research interventions for the participants, participating communities and the nation at large when research is over. In addition, neither audits to monitor approved research as a quality assurance measure; nor proper guidance and agreements to the transfer of samples and data outside of Botswana by international researchers, are done. The community sensitization research process is still weak and in its infancy, and there are no stringent measures in place to promote public awareness regarding health research and participants’ rights. These inadequacies have led to failure to diversify the regulatory functions of the committee. Instead functions currently concentrate on review of new applications and neglect other roles that are critical in the protection of research participants. For example at the moment, continuing reviews and amendments, annual reports from investigators, Data Safety Monitoring Board reports, Serious Adverse Events and close-outs of studies are not given the attention they deserve.
Conclusion: The analysis concludes that there is an urgent need to strengthen capacity in terms of training and diversifying human resources particularly in the ethical issues as well as sourcing for funding.
Streamlining of Regulatory Processes at M.D. Anderson Cancer Center Orlando
Authors: Jayne Goehmann; Meghan Cadwell; Joseph Charles; Lorraine Hickson; Christopher Anderson; Allisun Feazell

Background
The M. D. Anderson Cancer Center Orlando, Office of Clinical Trials currently has 120 actively accruing trials. Less frequently accounted for are the studies that are closed to enrollment. Once a protocol is closed to enrollment, the clinical requirements become less stringent, but the regulatory maintenance remains the same. The Regulatory Coordinators are responsible for an average of 34 studies each. In order to ensure accuracy and efficiency we have streamlined the program and divided specific tasks per project coordinator. In taking all regulatory duties away from the Clinical Research Coordinators, it allows their focus to remain solely on patient screening, enrollment and patient care.

Description of Program
When a new clinical trial is proposed, the regulatory process begins with the Billing and Contract Project Coordinator. This coordinator manages clinical trial contracts, budgets, research billing, peer review and regulatory study start-up. Upon peer review and approval from the Research Advisory Committee the protocol is assigned to a project coordinator. Major regulatory activities, including initial submissions, amendments, monitor visits, and consent translations, remain the responsibility of the assigned project coordinator. Within the regulatory team M. D. Anderson-Orlando employs a Consent Editor that drafts and edits consents according to the local IRB requirements and communicates closely with the entire research team.

Both the IRB and the Office of Clinical Trials have found efficiency in issuing IRB approvals to one Project Coordinator who processes the documents and provides notification to the sponsors and research staff. This includes electronically updating revised informed consents, protocols, and investigator’s brochures in a secured and shared network folder. Across the field of clinical research, many have found Investigational New Drug safety reports to be voluminous and time consuming. There was a vast reduction of time on each project coordinator when this task was assigned to one individual. Pairing tasks that are interconnected allows for a more efficient process of capturing data. The responsibility of local adverse events and protocol deviations is combined with responsibility of the patient database and accrual reports.

Another area we have identified for streamlining is continuing reviews and terminations as well as internal quality monitoring. Due to the cross coverage for each study, it is imperative that communication among the regulatory staff be frequent and detailed. Weekly meetings take place to ensure all aspects of studies are current. This structure would also not be possible without each team member having access to timely and reliable information that is housed in several key databases. The Office of Clinical Trials at M. D. Anderson Cancer Center Orlando has benefited a great deal from this streamlined structure. It has not only enabled the regulatory staff to efficiently carry a higher volume of studies, but more importantly has created a system for consistent and accurate documentation.
Streamlining the Administrative Review Process

Authors: Anuradha Diekmann, MPH, CCRP; Linda G. Halstead, MA

Background
Institutional Review Board (IRB) members have been overburdened with administratively reviewing expedited and exempt submissions and renewals. Turn-around times for protocol review and investigator attitudes toward the IRB could also be improved.

Description of Program
Definition of the Intended Outcome: Decrease turn-around times for protocol review, establish written guidelines for consistent reviews, and improve customer service and investigator attitudes toward the IRB/Office of Sponsored Research (OSR.)

Tools:
- Customized IRB application form for archival retrospective data, incorporating pertinent Health Insurance Portability and Accountability Act (HIPAA) questions
- Expedited and exempt submission checklists
- Expedited and exempt reviewer’s checklists to guide subcommittee review and provide federal, state, and institutional guidance and verify consistency of content across documents
- Continuing reviewer’s checklists
- Informed consent document checklist to assist investigators/coordinators and reviewers ensure that federal, state, and institutional requirements have been fulfilled.

Administrative Initial Review Standard Operating Procedure Formation of subcommittees:
- Established subcommittees of IRB members (one general and one in collaboration with the Department of Psychology), both including the IRB Administrator, to review submissions qualifying for expedited review per 45 CFR 46.110.

The research community was informed of OSR’s efforts to restructure review processes through:
- The homepage of the LLU Window on Research website
- A monthly “Researcher’s Alert” e-mail sent to all investigators and coordinators
- During educational events, lectures, and customized departmental trainings

Evaluation Method & Outcomes: Evaluation of this process is ongoing. OSR has received positive feedback from investigators and coordinators. Customizing tools to review expedited and exempt submissions can help your institution increase productivity, create a culture of compliance, and foster positive relationships with the research community.
Streamlining the IRB Review Process: Accountability, Consistency and Simplicity

Authors: Tracy Ziolek, MS, CIP; Yvonne K. Higgins, CIP; Megan Kasimatis Singleton, JD; Barbara Santiago, CIP

Background
Common complaints regarding IRB review from the research community are timely processing and the arduous process of submitting an IRB application. These problems are often compounded by the requirement for research review by several other entities. In response, the Penn IRB initiated several improvements to streamline the review process: (1) The IRB developed a benchmarking system with specific goals for timely processing; (2) The IRB assisted in developing an electronic submission system which allows concurrent submission to the IRB and other review committees; (3) The IRB implemented a sophisticated process for review of IRB applications including the use of screening checklists and encouragement of IRB member communication with researchers prior to IRB meetings.

Description of Program
The benchmarking system provides goals for staff when processing applications and correspondence, which results in similar processing times by all staff. The goals cover a range of IRB staff actions, including, but not limited to, time from receipt to entry into the database, time for completion of review for exempt and expedited studies and time from review by the convened IRB until the letter is drafted to the research team. In addition, completeness checklists have provided a common screening process for the IRB staff to determine if an application is complete. The electronic IRB application system provides a user-friendly, systematic application that reduces missing items from IRB applications and informs relevant review committees when an application is ready for review.

Outcome:
Average IRB processing time has decreased from 46 days to 22 days as a result of process improvements while the quality of review has continually improved. This is reflected in the favorable impression of the research community regarding the IRB. The benchmarking system provides staff with a common goal for timely turnaround of materials and provides IRB leadership with metrics for continuous quality improvement. The electronic IRB application system was recently recognized as an honorable mention recipient of the University’s Model of Excellence Award.

Suggestions for future usage:
The IRB will continue to use the benchmarks in place for timely processing and the tools provided to complete the pre-review process. The electronic submission system will be used to further streamline the IRB application process.

Suggestions for other sites:
The mystique of IRB processing time is reduced and the IRB staff is more aware of the expectation for turnaround time with benchmarking. Reviewer tools and implementation of an electronic review system will also benefit IRB processing.
Student IRB Service Learning: Measurable Impact on Consent Form Readability
Authors: Maria D. Mileno; Jared R. Schott

Background
Lengthy and complex consent forms for humans subjects research are often difficult for the average reader. Eighth grade students interested in medical research offered community service hours to read, edit and summarize consent forms to improve readability.

Description of Program
Eighth grade students met monthly to review edit and summarize consent forms submitted for approval. The Chair submitted substantive comments for consideration during the monthly IRB meeting. Students created one page quizzes to test readers on the elements of informed consent for each proposal. At the end of this school year a panel of teachers read 16 summaries and full consent forms and took the quiz. Data analysis is in progress. We have asked investigators to offer summaries for subjects who enroll in lengthy and complex studies. This service learning process offers assistance in the creation of understandable summaries and provides insights for young minds interested in medical research.

Additional Information
All names of investigators and sponsors were omitted. Data analysis is in progress.
System For The Registration and Monitoring of Clinical Trials in Peru
Authors: N. Espíritu; S. Sánchez; J. Sandy; F. Canchihuaman; P. García

Background
Purpose: To improve registration and monitoring of clinical trials (CT) conducted in Peru, as well as to improve information availability by promoting access to knowledge, which is a public good and an ethical requirement. Objective: To implement a system of registration and monitoring of clinical trials (SIRMEC) in Peru.

Description of Program
Methods: This is an operational research study, focused on launching and monitoring the impact of SIRMEC, available via the National Institute of Health of Peru (INS) web page. The system is open access, was designed in April 2007 and launched in July 2007. A list of indicators and a user satisfaction survey were also designed for clinical trial monitors, coordinators, data managers and administrators.

Results: SIRMEC allows electronic registration of CT, follow up of the approval process until final approval. It also issues alerts for process monitoring, has a module for the public to access CT information ongoing in Peru and offers contact information with the investigators. Until 15 June 2009, 20,224 users have accessed the SIRMEC information. Before SIRMEC was implemented, there was no control on timelines but currently the average approval process of a CT takes 40 days. SIRMEC has allowed for real-time statistics, comparatively, the number of registered CT has risen from 73 in 2003 to 132 in 2008. The user satisfaction survey showed that at least 70% were either satisfied or very satisfied with SIRMEC, and provided suggestions that are currently being evaluated.

Conclusion: SIRMEC has allowed for the improvement of the process of approval and monitoring of clinical trials in Peru, and has helped information transparency. It was also recognized as a good government practice for Peru.
That's a Wrap: Using Film to Educate About the Practical Aspects of the Informed Consent Process
Author: Halle Showalter Salas, BFA, MPhil

Background
Despite the unquestioned importance of informed consent in the research enterprise, the practice of obtaining consent remains a matter of concern. Federal regulations governing research with human participants dictate the specific content required for the informed consent process, but provide little guidance regarding "how" consent should be obtained and fail to address the practical issues that clinicians/researchers encounter as they engage families and research participants. Traditional curricula and training materials in research ethics focus on the content of informed consent, but rarely speak to the many practical factors that make an informed consent process both ethical and valuable for families.

Description of Program
Seattle Children’s Research Institute created two films-- one with a specific research focus and the second with a communication focus particularly centered on engaging families with limited English proficiency. The films, Paging Dr. Peter and The Journey of Captain Nat take a fresh and humorous approach to everyday dilemmas encountered in the informed consent process. Both use cleverly written dialogue and surreal situations to entertain, educate and connect with the audience. Approximately 15 minutes in length, each will be posted online and available to any institution that wishes to utilize them. Accompanying the films are facilitator’s guides that provide a brief overview of each film, aid a designated facilitator in presenting the film to a group and provide help for leading a discussion surrounding the issues presented by the films. The guides include background information, educational goals when presenting the film and facilitating a discussion, synopsis of the film, suggested reading for the facilitator and an outline of discussion topics followed by questions to aid in discussing the topic. Following each question is relevant information the facilitator may want to ensure is included in the conversation with the audience.

During the creation process, feedback was collected from numerous groups interpreter services, bioethics, research administration, investigators and clinical staff to make the films inclusive of a variety or views and educational needs. Once available online, a feedback form will be sent to individuals downloading the resources. The form will assess the content of both the films and the facilitator’s guides. It will also provide information about the types of institutions and groups seeking such resources and what future resources may be helpful. Investment in educational ventures of this type may provide an efficient and effective means of training staff about the practical issues related to communication and informed consent, greatly enhancing ethical research practices and the experience for families and participants. Institutions should supplement existing educational efforts by implementing programs that specifically examine the practical aspects of the informed consent process including improving communication with families.

Additional Information
The films will be playing during the poster presentation.
The Broad and Blurred Boundary Between Quality Improvement (QI) and Human Subjects Research
Authors: M.M. Klote; J.T. Lenert; A. Chang; C.E. McQueen

Background
In distinction to human subject research, QI projects are defined as systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings. The distinction between QI and research is important, because QI projects typically do not require review by an institutional review board or formal documentation of informed consent at the individual level. We anticipate that the number of QI projects conducted at our institutions will increase in the future, given the military, Joint Commission and the American College of Graduate Medical Education emphasis on improving quality of care. At our institutions, QI projects undergo a screening procedure and are registered by each Quality Management Division (QMD). Although key federal agencies disagree about the boundaries between QI and research, we believed our procedure to screen QI projects was adequate to make the distinction.

Description of Program
To encourage QI projects and promote their visibility, we included these projects for the first time as a separate category in our 2009 annual research competition. Submission to the competition is voluntary and all QI abstracts were accepted for poster presentation.

Results: Twelve entries were submitted by the authors in the QI category. A panel of judges knowledgeable in the distinctions between QI and Research reviewed the 12 projects. There was consensus among the experts that 5 projects clearly met the definition of QI. Five had features consistent with human subject research, placing them within a boundary zone between QI and research that would have been appropriate for review under the exempt/expedited IRB pathway. Two were clearly research projects, one of which had undergone IRB review while the other was submitted with review pending. Experts disagreed about the categorization of the five that had features of both.

Conclusion: The proportion of projects that were misclassified either by the investigator or the QMD was larger (range: 1-5/12; 8-42%) than expected. The differing opinions among our expert panel highlight the need for improved guidance on this issue. By including QI projects in our competition we created an opportunity to educate personnel on distinctions between QI and research.
The Challenges of Instituting a National Ethics Committee and an Institutional Review Board in Human Research Ethics in Developing Countries

Authors: Robert Draper, BSc; Jemee K. Tegli, BA; Stephen B. Kennedy MD, MPH; Edward Smith, MPhil; Cecelia Morris, MSN; Esther George-William, MSN

Background

The challenges in operating two co-equal supervisory bodies which have the responsibility of approving human subject research projects poses serious complex problem in resource – constrained developing countries, especially in Africa. Even though their respective scopes of operation do vary, it still encompasses social, political and legal implications. While one may assume that these two entities should co-exist and complement or collaborate in the review and approval process, too often the NEC tends to claim of being the legitimate body to review and approve research studies that deals with human subjects.

Description of Program

There are usually public healths, academic and/or medical infrastructure which serve as entry points for effective operation of IRBs in developing countries. In the case of Liberia, the (UL-PIRE) is housed at the Medical College of the University of Liberia where a 5-year behavioral-driven research study on HIV/AIDs prevention amongst adolescents in Liberia is being implemented. International guidelines and many nations’ laws mandate that research with humans requires prior approval from a research ethics committee or IRB. A new study in PLoS Medicine examined how well these research ethics committees are functioning in Africa. In the study, by Nancy Kass, Adnan Ali Hyder (both at Johns Hopkins School of Public Health and Johns Hopkins Berman Institute of Bioethics) and their colleagues in ten African countries, researchers reported experiences of 12 different research ethics committees (RECs) from nine African countries. They reported a number of challenges faced by ethic committees, including inadequate funding, staffing, and training. Many said their committees lacked expertise in considering the ethical aspects of the proposed research, which led to greater focus on scientific aspects and budget. Some research ethics committees felt that it was hard to give a truly independent assessment of the proposed research, because approving the research would lead to greater funding going to their own institution. Respondents also mentioned several strengths of their committees. For example, many RECs have been formed recently, reflecting that ethics review increasingly is becoming the norm in Africa; further, the longer a committee has existed, the more likely it is to pay close attention to ethics and to have predictable funding. Governmental agencies responsible for health and social services are generally aware of the operations of IRB’s in developing countries in Africa. The must be linkage existing with IRBs and NECs in approving highly scientific research protocol for studies in developing countries. For example in Liberia, the Ministry of Health and Social Welfare through the NEC (yet to be established) is charged with the responsibility to regulate all IRB related activities in Liberia.

Additional Information

It is highly recommended that all IRBs in developing countries should further seek accreditation with other international ethical boards to authenticate research studies they undertake in their respective countries. Such exercise is for the sole purpose of networking and an opportunity to share experiences regarding best practices and/or ethical standards. NECs and IRBs in Africa should be encouraged to meet regularly to discuss pertinent issues associated with the work they do. In Liberia, the IRB meets at least once per month. It is further suggested that IRBs in Africa should share their knowledge and expertise with public health institutions of higher learning and medical facilities involved in human research studies.
The Contribution of the Kintampo Health Research Centre-Institutional Ethics Committee in Promoting Human Research Ethics among its research professionals

Authors: Dzasi Kafui Kwasi, MSc (Student), BSc; Mahama Nashiru Emmanuel, BSc

Background
The Institutional Ethics Committee of the Kintampo Health Research Centre is committed to conducting cutting-edge, multidisciplinary research; helping to train the next generation of leaders in bioethics; prepare trainees for the ethical challenges of professional and civic life and contributing to more ethical public policies regarding clinical issues, problems or dilemmas of clinical management and the human subject research. Due to this fact, it was necessary to create a training program aimed for research professionals.

Specific Challenges: Poor attendance at Institutional Ethics Committees events, inadequate preparedness of professionals to handle complexities that characterize justice and beneficence desirable for research involving human subjects and communities, limited resources, Professionals difficulties determining when projects constitute human subjects research activities.

Description of Program
Intended Outcomes: To achieve the proper training of research professionals at the health research centre so that they can develop their functions in accordance with national and international parameters applied in the field of research ethics and, therefore, safeguarding the welfare of those involved in biomedical research studies when implementing health research protocols. In the light of the generally poor health delivery systems, the lower levels of education among research professionals and investigators became imperative. The IEC concluded that the training approach should be directed to the implementation of fundamental ethical principles and training in research methodology and, as a result, an initial training program in this area has been established. The training applied participatory approaches including overviews, case studies, and discussion groups and with special panels for some topics convened.

Evaluation: With the maiden training program organized, a total of 42 research professionals were trained (approximately 50% of all the members). In this sense, although it is still premature to assess the impact of this program, significant progress has been obtained, affecting directly the operations of the research centre.

Suggestions for Future Program Usage at Home Institution: This program is in a process of constant improvement, required to obtain its consolidation. Nevertheless, it is necessary to allow sufficient time for its implementation, and over all, to be clear that the results will be observed over the medium term.
The Ethical Implications of Engaging in Decolonizing Methodologies in a Canadian Aboriginal Reserve
Authors: Robert J. Schinke, EdD; Duke Peltier

Background
The immediate presentation provides a positive ongoing contextual example of research where an ongoing partnership has been developed and maintained among a Canadian Aboriginal Reserve and mainstream faculty members at a university in the same region. Though conceptually there are several guidelines regarding how to proceed in research with Aboriginal peoples authored in Canada, Australia and New Zealand, there are fewer examples that forefront Aboriginal voices and practices as part of such research in an integrated manner. The objective through the immediate presentation is to provide a contextual description regarding how indigenous methodologies were (and can be) employed as part of a decolonizing methodology within an ongoing research project where practices and roles are negotiated and renegotiated when the community members assume self-governance of what is achieved through the research. The present research presentation reflects a collaboration through research in its sixth year of existence in Northern Ontario, Canada.

Description of Program
Decolonizing methodologies are meant to play an emancipating role through research practices (see Smith, 1999). Where traditional methods might be evaluated based on scientific merit and various types of validity contingent on the methodology (Maxwell, 2002), the current project was evaluated based on culturally informed criteria deemed relevant from within the Wikwemikong Unceded Indian reserve (see Schinke et al., 2009). The project was developed to evaluate the reasons underlying high drop out rates in community organized sport and activity programming among Wikwemikong youth. On-reserve Aboriginal youth have been documented as being an at risk cohort with rates five to seven times higher in terms of incarceration, substance abuse, obesity and suicide (www.gc.ca). Through the project, the researchers partnered with community designated co-researchers, including the sport and recreation director, the director of the community’s youth center, two community elders, and several university youth assigned as research assistants.

The methods employed to glean the desired information included community led talking circles where leaders were assigned based on age cohort, monthly community meetings, indigenous forms of data analysis and indigenous terminology, co-authoring and presenting for international sport science and indigenous audiences. The methods in themselves, the focus of this presentation, were selected to forefront local Aboriginal practices in place of mainstream methodologies and as such affirmed previously marginalized voices through the project.

The evaluative criteria employed for the qualitative methodology, beyond conventional post-positivist guidelines included transformational validity where the quality of the project is evaluated based upon transformational and catalytic guidelines (i.e., positive changes within the intended community). Presently, the Wikwemikong have assumed control of the project’s derived programming and as such the project is now self-governed and led by and within Wikwemikong. From what is gleaned, researchers will be provided with a positive example of how decolonizing methodologies, a derivative of participatory action research can be employed to support positive change through research projects among oppressed peoples. Through the immediate contextual example, researchers will also glean a deeper understanding of how Canada’s CIHR Guidelines for Aboriginal Research can be employed from the ground up within an oppressed community. Through such research, the goal is to enhance long-term cross-cultural relations, all the while developing research that is emancipating.

Additional Information
Decolonizing methodologies if engaged in with cultural reflexivity forefront the research practices and
expertise within the intended oppressed community. Through decolonizing methodologies the intent is to place positive transformational change and enhanced trust among the cross-cultural research team as the primary objectives. When contrasted with indigenous methodologies conventional mainstream research practices can subvert the voices of indigenous peoples.
The Great American Cookie Experiment Research Program: A Strategy to Support Novice Nurse Researchers to Navigate the IRB Process

Author: JoAnn Mick

Background
Barriers to research conduct and effective support for protocol development can create challenges for healthcare organizations striving to develop quality nursing research programs. Both administrators and Institutional Review Board (IRB) members desire the design and completion of scientifically and ethically sound studies. Although nurses may have participated in basic research and ethics courses in their nursing programs, nurses in clinical settings often describe research knowledge deficits. Interested nurses acknowledge little opportunity for hands-on experience to develop research skills and competencies. Nurses may express fear or lack understanding about the IRB review process. As administrators seek to establish evidence-based practice organizational cultures, education and support must be provided so nurses are able to critique research articles, evaluate best practices, replicate/design studies, write scientific and ethically sound protocols, navigate the protocol review process, and conduct research. Educational activities can proactively address the scientific and ethical perspectives assessed by protocol reviewers to support timely IRB approval and provide positive research experiences.

Description of Program
A competency-based research program, The Great American Cookie Experiment, was implemented in a county healthcare system. Participants complete a Human Subjects Protection Course, attend monthly classes to learn the research process, collaboratively develop a protocol, obtain IRB approval, and conduct a survey of nurses’ taste preferences for 2 cookies. Educational sessions describe principal investigator and collaborators’ ethical and scientific responsibilities to assure protection of the rights and welfare of research subjects. Sessions related to protocol development address criteria in IRB reviewer checklists. An IRB Administrator with CIP credentials explains what occurs during the time period from protocol submission to notification of approval status, including description of an IRB panel, possible outcomes of review, and information to successfully navigate the review process. Nurses practice use of a data collection plan to identify and recruit study participants, obtain informed consent, and administer a research instrument. Hands-on experience in a supportive, structured program has provided opportunities for nurses to overcome research concerns and acquire knowledge and skills useful to study clinical practice-area interests. Competency self-assessment scores have increased from baseline to 6-months in the program. A 12-month assessment will be conducted at program conclusion.

Additional Information
Incorporating knowledge of human subject protection, explaining the IRB process, outlining principal investigator and collaborator responsibilities, and disclosing criteria considered by IRB members during research educational sessions can facilitate prompt approval of nurses’ protocols and create positive research experiences for novice researchers.
The VA Central IRB - Development Through the First Year of Operation

Authors: Annette R. Anderson, MS; Lucindia Shouse, MA; Lorna Harold, MBA; Hector Ramirez; Erica Doruska, MA; C. Karen Jeans, MSN; Rene Sutton, BS; Marisue Cody, MSN, PHD; K. Lynn Cates, MD

Background
The VA Central IRB was developed to improve the lives of veterans by enhancing the quality of human research protection in multi-site projects supported by the Office of Research and Development, Department of Veterans Affairs. The VA Central IRB does this by providing consistent expert ethical and scientific reviews while obtaining input from participating sites to ensure local context issues are addressed. By enhancing the efficiency of the review process, this model has the potential to facilitate faster translation of research results to the clinical environment.

Description of Program
The concept for a VA Central IRB was developed with the input of many experts within the VA and other organizations over a period of several years. Actual development took 18 months. During this time a Memorandum of Understanding detailing the various roles of the VA Central IRB and local sites was established; a Human Research Protections Program was initiated within the VHA Central Office; Board members were recruited and trained; standard operating procedures were developed; a “Mock Board” was conducted; and webinars were held for both local facility Research Office staff and investigators. The first official convened meeting was in August 2008.

The VA Central IRB new project review model involves a two-step application process. The first step is submission, review, and approval of a Principal Investigator (PI) New Project Application, followed by a 30 day comment period for all participating sites. The second step is submission, review, and approval of Local Site Investigator (LSI) applications containing site-specific information and updated model documents approved as part of the PI Application. Submitted local site comments are also reviewed at this time. The Board can accept a local comment and apply it to all sites; apply it to a single site; reject the comment; and/or require a change in the PI Application. Once the PI and LSI Applications are approved each site has 10 days to make a participation decision. If a site decides to participate, the study must then be approved by the site in accordance with local Research and Development Committee policies.

As of June 1, 2009, the VA Central IRB reviewed 13 studies involving over 75 sites. It continually refines its policies and procedures and is preparing to submit an application for AAHRP accreditation. It is anticipated that the model will continue to evolve as more and different types of studies are reviewed.
Tip of the Week
Authors: Cheryl Jamnick; Ellen LaChance; Cissy Brenner; Wendy Ulmer

Background
Challenges of providing board member reviewers with quick educational tips to help facilitate reviews, navigate through the electronic human subject research application system (eResearch), answer common questions relating to the IRB process, and keeping them apprised of changes to office procedures and policies is an ongoing process.

Description of Program
Specific Challenges: With the implementation of the new electronic human subject research application system (eResearch) and the quarterly upgrades (releases) required to continually improve the electronic system, it was apparent that day to day functions and short cuts discovered by IRB staff were not reliably communicated to all board members across the five IRBs. In the interest of assisting board members with the most efficient way to review submissions and navigate through eResearch, the “Tip of the Week” program was developed.

Program Approach: A power point ‘Tip of the Week’ presentation is prepared and displayed weekly in the meeting room as board members arrive. This approach was taken to access all board members at the same time. The presentations touch on a variety of subjects that are designed to provide assistance with reviews, decrease redundant review practices with the goal of improving turnaround time, and aid the reviewer in keeping abreast of changes in federal and State regulations, institutional policies, and office practices and procedures. The presentations are set on continuous play and last no more than 2 minutes to accommodate the staggered arrival of the board members.

Results: The “Tip of the Week” program was well received and board members frequently offer suggestions for different topics. Requests are also being received to provide additional viewings of the “Tip of the Week” after the meetings for those members arriving late.

Future Plans: Future plans are being made to use this “Tip” program in new board member training as well as other training programs within the IRB. This quick tip initiative could be a useful tool for quick and easy education tips in other institutions.
To intervene or not? Ethical Issues in Observational Research on the Informed Consent Process

Authors: J. Henriksen Hellyer; A.M. Dose; B. A. Koenig

Background
Ethnography is a useful technique for studying the informed consent process as it unfolds. Direct observation allows the observer to ask whether a consent process is effective for fully informing potential research participants. However, sometimes naturalistic observation uncovers problems in the informed consent process that raise ethical questions for the researcher. When the observer is conducting a formal research project -- rather than engaging in quality improvement or education -- the researcher must decide if she should intervene or simply continue collecting data for eventual sharing of results.

Description of Program
A multi-disciplinary team designed a qualitative study to examine the experience of participants being recruited for studies in cardiovascular genetics. Subjects included hospitalized patients who had experienced myocardial infarction symptoms and outpatients receiving physical examinations. Our research focused on the informed consent process itself. To understand patients' experience, we first observed interactions between potential research subjects and study coordinators as they moved through the informed consent process. Then, following the interactions, we interviewed subjects to ask about their experience. Some questions were designed to elicit participants' understanding of the parent study and others were meant to draw out their feelings and opinions about the experience. Subsequent qualitative analysis triangulates the direct observation with first-hand accounts from the subjects.

Ethical questions arose for the ethnographers. During an observation, one patient gave what appeared to be both verbal and nonverbal confirmation of understanding the study and its implications. The interview immediately following the consent process revealed that the subject actually had minimal knowledge of the study. In another instance, signed informed consent was obtained from a family member, not the research participant. Do such findings require intervention by the bioethics researcher whose study purpose is to collect information about the consent process? What criteria should ethnographers use when deciding whether action is morally required? We will present the dilemmas encountered during ethnographic fieldwork and provide an ethical analysis of potential responses to the problems we observed. Finally, we will offer suggestions to IRBs considering how best to oversee qualitative research protocols for the study of the informed consent process.
Tools, Templates, and Training for GCP Compliant Protocol Development
Authors: Gregg Fromell; Nancy M. Pultorak; Alyson M. Hettenbach; Ann N. Sieber

Background
The protocol is the guidebook for implementing and conducting a scientific investigation. Traditionally, protocol development education focuses on the scientific hypothesis and associated methodology and biostatistical design. Many times an investigator will use a research grant application in place of a Good Clinical Practice (GCP) compliant protocol. The protocol is distinct from a research grant. While the grant provides a broad overview of the study procedures, the protocol clearly defines and operationalizes the details of study implementation.

Description of the Program
Penn Medicine’s Office of Human Research designed a protocol template that incorporates the required elements of a study protocol dictated by ICH-E6 Good Clinical Practice Guidance. The Penn Medicine Protocol Template enhances protocol design by providing a framework for protocol writing that addresses the more operational aspects of a protocol in creation of a GCP-compliant protocol. Key elements of the Penn Protocol Template are: Introduction, Study Objectives, Study Design, Subject Selection and Withdrawal, Study Drug, Study Procedures, Statistical Plan, Safety and Adverse Events, Data Handling and Record keeping, Study Monitoring, Auditing and Inspections, Ethical Considerations, Study Finances, and Publication Plan. Each element in the template includes content guidance and in same cases example language.

The template uses functionalities in Microsoft Word to create automated formatting and generation of a table of contents. Various sections also contain suggested language that is compliant with federal regulations (e.g. safety section, adverse event reporting requirements, etc.).

Program Evaluation
Since its implementation in 2003, the use of the protocol template improves understanding of study management requirements and Good Clinical Practice standards, and speeds regulatory review by the Institutional Review Boards (IRBs) and the Food and Drug Administration (FDA).

Next Steps
The OHR has utilized this approach to create additional templates to support compliance with applicable guidelines and regulations, such as IND and IDE applications.

Suggestion for Implementation at Other Sites
The OHR will make this template available to other institutions as we are all partners in promoting compliance and operational standardization as it lends itself to human subject research protections.
Tracking Database Views to Minimize Errors and Expedite Study Submission Processing Time
Authors: Sharon Ankrah, BS, CCRP; Melanie Fleming, BS

Background
IRBs at high-volume research institutions receive multiple submissions each day. For institutions it is imperative that a system be developed to minimize errors and expedite study submission processing time. The goal is to facilitate better communication between the institution and research community, as well as helping the analyst prioritize study submissions such as continuing reviews, amendments, and adverse events (AE), based on immediate need.

Description of Program
To accomplish this goal, the following database views were created at the Vanderbilt IRB, to show portions of the IRB submission process that need to be addressed on a daily/weekly basis: Team E-Inbox; Continuing Reviews; Studies due to expire; AE’s No Chair Verified Date; Committee Action Letter (CAL) Follow-up; Letters without Dates; Pre-Review; and Working Agenda. The intended outcome is to minimize errors and expedite study submission processing time.

In our analysis, we identified outcome measures that can be used for evaluating the success or failure of monitoring views: processing time, number of errors, and customer satisfaction. To determine if monitoring the views is successful, the overall processing time of submissions is evaluated to ensure studies are being processed within the target time set for each submission type. In addition, a number of audit systems have been put in place to verify a decrease in the number of errors when processing submissions. These include immediate feedback from the process improvement team, supervisors, team leaders, as well as periodic feedback from regulatory agencies such as FDA, and AAHRPP. Customer satisfaction is evaluated through increased accuracy in communication with the research community.

This program may be implemented at any institution whether the submission and processing system is electronic or paper. There is minimal impact on workflow, implementation cost is low, and once executed it offers a constant cycle of assessment, which allows for continuous process improvement.
Using Current Technology and Interactive Dialogue with IRB Documents Committee to Create Simplified Forms
Authors: Ellen Schellhause, MSLS; Joann Glacken, MA

Background
There were frequently voiced comments from PIs and IRB reviewers stating that the IRB forms and instructional tools were too cumbersome, complicated, and confusing. A Documents Committee of researchers, administrators, and IRB members was formed to re-draft forms that were AAHARP compliant, yet had simplified language and format.

Description of Program
The committee came together in a conference room, using a projector and a laptop. The documents were edited in real time with a member at the keyboard so everyone could see, comment, and discuss as work began to rewrite forms. They brought different perspectives together as the new forms and instructional tools were created and edited with a simpler and more logical flow. Forms were dissected in a brainstorming effort to reduce the problematic language in a systematic way and to create documents in understandable format rather than being lofty. With actual users in the meeting, ideas, perceived barriers, and observations from the full IRB committee sessions were taken under consideration. The addition of check boxes was added to create and incorporate a decision tree that flowed on the form. A separate checklist page was drafted to correspond to each form so the researcher could provide all required information, eliminating speculation and guesswork on what was being requested.

Evaluation: User feedback – newly created forms were given to experienced researchers who had used older forms. Their feedback was critical to making corrections on forms, which would be posted on IRBNet. Reviewer, PI feedback, and IRB committee feedback was positive.

Suggestions for future programs usage: These vibrant sessions worked well and productivity was high. We will continue to listen to researchers and reviewers to keep document language simple and usable. The IRB Committee will review and revise forms and checklists as necessary, continuing to apply principles and surveillance to accomplish the IRB mission, assisting researchers by keeping language in forms simple.

Suggestions for implementation at other sites: This process was not difficult to implement and can be easily duplicated at other institutions depending on the need.

Additional Information
This program format could be used as a "hands on" teaching lab to teach others how to create, simplify, and evaluate IRB submission forms.