Programmatic Poster Abstracts from the 2010 AER Conference: Uniting People, Principles, and Practices

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When "Minimal Risk" is Not Enough - A Discussion Addressing the Need to Minimize Risk in Pediatric Research
A Model of Building Trust for the Inclusion and Protection of Racial/Ethnic Populations in Research
Kaiser Permanente Southern California
Armida Ayala, PhD; Ijeoma Nwachuku, PhD; Alva Moreno; Francisco Morales; Vonee So; Daria Galindo; Isabel M. Sanchez

Topic: Special Populations

Problem/Issue Statement
The KPSC IRB trains its non-affiliated members who are representative and/or advocates of racial/ethnic groups to apply the principle of justice and actively lead the review of research protocols involving vulnerable populations. Some racial/ethnic populations have a disproportionate rate of poverty, disease low reading levels, and high rate of diseases that renders them vulnerable. The rise in chronic disease and genetic research among racial/ethnic populations calls for an in-depth look at the principle of justice. Researchers must implement culturally responsive strategies to justly include racial/ethnic groups, and their communities as well. Likewise, non-affiliated members must build cultural capital by bonding and bridging within the research institution to protect racial/ethnic populations, and their communities when deciding whether the burden of the research they review will be appropriately borne.

Description of Program/Research

Methods
We developed an individualized training that provides coaching to non-affiliated community members and advocates on how to lead and actively participate in the review of protocols involving vulnerable racial/ethnic populations. The training includes: 1. Knowledge of the principle of justice and application of the regulatory structure, process and outcome of the informed consent and research methods. 2. Understanding of building cultural capital. Non-affiliated IRB members, advocates, and researchers, are provided individual guidance on how to bond and bridge and treat racial/ethnic populations as a cultural force that increases trust and strengthens relationships. 3. Participation in the Vulnerable Population IRB Subcommittee. IRB members provide expert review and consultation on research applications involving racial/ethnic groups and other populations in the context of vulnerability. 4. Awareness of interactional achievement-interpersonal rapport, exchange of information, empathy and trust-and how it is accomplished or undone based on specialized cultural resources that non-affiliated members bring in combination with researchers’ fostering of and receptiveness of those resources.

Program Evaluation
This program is evaluated by an individual assessment to determine if educational goals have been met. The coach provides feedback on an ongoing basis and as requested.

Future Use
The KPSC IRB will share the training inter-regionally with seven KP IRBs.

Suggestions for Implementation at Other Sites
This training may serve as a guide to other IRBs and can be easily implemented with existing educational resources. The training builds cultural capital because it leads IRBs with diversity by actively involving the participation of racial/ethnic groups and advocates in the protection of human research participants they represent.
A Pilot Project: Quality Assurance of IRB Review (Exempt and Expedited Study Submissions)

NYU School of Medicine
Helen Panageas; Steven Keenan; Joy Jurnack, RN

**Topic:** QA/QI

**Problem/Issue Statement**

The program is intended to assure the quality of IRB reviews. The purpose of this project is to determine if a systematic program can effectively evaluate the quality of exempt and expedited reviews. The goal of the pilot program is to establish a long term program that will evaluate and assure the quality of IRB reviews and help improve the review and documentation of 45 CFR 46.111 findings by ensuring the accuracy, completeness and consistency of IRB reviews.

**Description of Program/Research**

A random selection of newly approved expedited and exempt studies were evaluated from September 2009 and April 2010. Approximately, 30 projects were reviewed over a 10 week period. The evaluation included review of final approved protocol, informed consent and any other supporting documentation, as well as internal review checklists. The records were reviewed to assess indicators for Completeness/Accuracy/Consistency as follows:

- Completeness
  - Final Review checklist completed assessing 45 CFR 46.111 Findings
  - Pre-review checklist completed
  - Communication with PI and Research Noted in record - Noted Resolution found in record
  - Process follows internal SOPs for handoffs, coverage, processing of submission
  - Accuracy: Correct designation of expedited or exempt.
  - Correct designation of categories of review for expedited and exempt
  - Regulatory Criteria found and documented:
    - 45 CFR 46.111 findings
    - Informed Consent document 45 CFR 46.116 or designation of waiver of consent
    - Identification of vulnerable populations and subpart findings when necessary
    - Assessment of information for 1 or 2 parental consent, where applicable, noted in approval notice.
  - Consistent:
    - Decisions on category and type of review within each board and across all boards
    - Process is followed for documenting determinations

Data Analysis is still ongoing at this point. Data will be crossed to Division of Education and Training for use in the development of new education and training sessions for expedited and exempt reviewers. Once fully established the program will be also be applied to Full Board reviews.
A Practical Approach to Addressing Regulatory Deficiencies in Human Subjects Research: The Development of a Comprehensive Corrective Action Plan
Marion Olson, CIP; Wanda Quezada, CIP; Evanna Thompson, MPH, CIP; Marci Montemayor, CIM; Martha J. Matza, MS CIM CIP

Topic: Regulatory Compliance

Problem/Issue Statement
Audit and monitoring reports are routinely utilized by sponsors, granting agencies, Institutional Review Boards (IRB) and/or institutions in human subjects research to serve as a guide to investigators to ensure the research is being conducted appropriately. The outcomes of these reports can leave investigators and IRBs wondering how to best address the regulatory deficiencies that have been identified. A corrective action plan (CAP) is a written response generated by the investigator to address these deficiencies. Many investigators struggle with the development of an appropriate comprehensive CAP that encompasses all aspects of the research. IRBs can assist investigators by providing guidance, including a standard template of primary points to be included in the CAP.

Description of Program/Research

Intended Outcome
CAPs are frequently used to address deficiencies that generally fall into four main categories, which include non-adherence to the study design, lack of timely reporting, incomplete consenting processes, and inadequate management of conflicts of interest. The CAP should define steps that will prevent or minimize future occurrences associated with deficiencies and include the following Action Phases (AP): 1) root cause assessment; 2) extensive evaluation; 3) responsible owner determination; 4) devising measurable actions to prevent the deficiency; and 5) defining a plan to monitor the progress of the CAP.

Description
During the assessment and evaluation phase, the investigator should perform a thorough review to determine each deficiency and its impact on the research, data integrity, and why the deficiency is occurring and possible resolutions to the deficiency. Determining the responsible owner is integral to the successful implementation of the CAP. Owners are individuals directly involved with the research and should include one or more of the following; the investigator, collaborators, department or divisional chairs and/or other research staff. The CAP should be geared towards the achievement of the outlined objectives and be written to include realistic timeframes, delineating when each action should be completed and by whom. Finally, adherence to the CAP should be monitored. If the objectives of the CAP are not being met, the CAP should be revised to effectively address issues. Monitoring reports should be submitted to the IRB and/or Sponsor.

Suggestions
Investigators should be cognizant of the federal, institutional and sponsor policies. Unless there is an immediate risk to research subjects, the CAP should not be implemented until IRB and Sponsor approvals have been obtained. The CAP should be filed in the regulatory binder and include periodic progression reports to the IRB and the Sponsor. It is integral that the CAP include a mechanism to validate that the objectives are being met to ensure the continued protection of research subjects participating in the clinical trial.
A Systematic Review of Variability in Subject Compensation in Research Protocols at a Single Institution
Laura Kimberly; Alex Noury; Marjorie Gillespie; Michael Chapple; Anne E. Gupman, MA, CIP; Jennifer Morris; Rachel Topper-Greco; Nanette Suksta; Donna Howard; Catherine Little; Pamela Kearney; Barbara Karp

Topic: Regulations and Guidelines

Problem/Issue Statement
Compensation for research subjects is an accepted practice to offset the inconvenience and time of participation. The compensation plan is proposed by the study investigators or sponsors and should be commensurate with the planned procedures. Compensation should not be construed a benefit of participation and cannot be used to offset study risks. IRBs are charged with reviewing the compensation plan to assure that the amount of payment and scheduling of payments will not be “…coercive or present undue influence” [21 CFR 50.20]. No regulations or Federal guidance provide suggested compensation amounts for specific procedures or time. Although many institutions have standard compensation amounts, consistency across studies may be difficult to achieve. Each research project has unique features that make comparison and consistency difficult. Lack of consistency within and between institutions undermines equitability and can lead to competition between institutions and studies to attract participants by offering increased compensation.

Description of Program/Research

Methods
In this study, we reviewed U.S. regulations and institutional policies on compensation amounts. We reviewed protocols and consent forms active in 2009 from our own IRB for compensation amounts in relation to the nature of procedures, level of discomfort and time commitment required.

Results
This study will yield information on the variability in compensation amounts between protocols within a single institution. Analysis of this data will allow us to better understand factors that contribute to compensation variability. The data will also allow us to confirm that the payment amounts are in accord with Federal policy and institutional guidelines.

Next Steps
The results of this study will be used to develop institution-specific standards and guidance to promote consistency and fairness in compensation types and rates across studies.

Additional Information
This research was supported by the Intramural Research Program of the NIH.
An Electronic Model for Document Sharing to Increase Efficiency of Multi-Site Reviews: Central Shared Resource (CSR)

Vanderbilt Human Research Protection Program
Jennifer G. Beadles, CIP; Gordon R. Bernard, MD; Todd W. Rice, MD, MSc; Denise A. Roe, MSM, RAC, CCRP, CIP; Julie A. Ozier, MHL, CIP, CHRC; Paul A. Harris, PhD; Kirstin Woody Scott, MPH

Topic: IRB Operations

Problem/Issue Statement

National stakeholders involved in multi-site research have called for novel methods for eliminating the duplication of effort, cost, increasing efficiency, and developing alternative solutions that permit shorter review cycles for multicenter human research. The current multi-site review model is time and resource intensive as studies undergo multiple changes during the review process, which may not be congruent at each site. This consequently tends to delay, and sometimes even prevents studies that are of high quality from being initiated at one or more sites in a given network. The Vanderbilt Human Research Protection Program (VHRPP), with the dedicated support of Vanderbilt’s Biomedical Informatics Department, proposes addressing this national problem and unmet need by developing and establishing a central electronic document sharing resource, with future implications for utilization by multiple institutions nationwide.

Description of Program/Research

Currently, the VHRPP has implemented a resource sharing policy to allow for sharing of approved consent forms, approved study documents, redacted meeting minutes, 45CFR46 criteria determinations, waiver of consent criteria and determinations, and vulnerable population determinations. To further strengthen a resource sharing concept, however, the VHRPP’s primary objective is to establish an electronic resource for data and document sharing across IRBs to facilitate reviews of multi-site studies to avoid inadvertent or preventable variation and promote consistency. We will develop a secure electronic central shared resource (CSR) to manage and store IRB reviews and associated documents. This will be accomplished by leveraging the technical and informatics expertise of Vanderbilt’s Research Bioinformatics division, which has extensive experience and nationally recognized success in the development and implementation of shared secure multi-institutional data repositories (e.g., REDCap, ResearchMatch.org). We propose to develop the CSR via the following key operational elements: 1) Build a secure website that will allow for the posting and sharing of documents (e.g. protocol registration process, plan for data access, and data quality assurance); 2) Formalize policies and procedures related to registration and access; and 3) Develop training modules that ensure proper utilization. We will also consult the experience of other partnering institutions, as well as the technical experts from such institutions, wishing to contribute to the development of this novel technology resource.
Analysis of an Institutionally-based Subject Injury Compensation Program
University of California, San Francisco
Mr. Carroll Child, RN, MSc; Mr. Bruce G. Flynn, MS

**Topic:** Ethics and Risk Assessment

**Problem/Issue Statement**

Despite a 2002 Institute of Medicine report calling for research organizations to provide compensation to research participants directly injured in research, in the absence of federal or other national regulatory or accreditation requirements mandating the provision of compensation to injured subjects, work by Steinbrook (NEJM, 2006) found that only a small minority (16%) of the 102 academic medical centers surveyed had policies for the provision of free care or treatment for study-related injury. At the same time, there is a paucity of information about the number of such injury cases occurring in academic research enterprises and the actual cost of responding to such cases through an institutionally-based subject injury treatment and management program.

**Description of Program/Research**

**Intended Outcomes**

To evaluate the incidence and treatment costs of subject injury events within the Subject Injury (SI) Program at UCSF and the cost differences between research injury claims that were litigated versus those managed through the campus SI Program. METHODS In close partnership with the University of California Office of the President, the University of California, San Francisco (UCSF) established in 2005 a campus-based Subject Injury (SI) Program to apply the existing University of California’s system wide Subject Injury Policy to subject injury cases as they arose from UCSF-affiliated clinical research. In June 2010, the UCSF SI program conducted a retrospective review and cost analysis of SI claims filed between January 2006 and January 2010.

**Results**

Of the total claims evaluated (14), six (or 43%) required payment costs to bring them to settlement and the remaining SI claims filed (8 or 57%) resulted in no direct costs to the SI program. 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. Although litigated claims were relatively infrequent (21%), settlement costs were on average more than 20-times higher than non-litigated claims settled within the SI program.

**Discussion**

While further inter-institutional comparative analysis is needed to better characterize the practical value programs designed to compensate participants for research-related injury, our review suggests that significant cost benefits may result when injury claims/cases are managed within an institutionally-based SI treatment compensation program. Cost savings may be due to a number of factors that include: 1) a relatively low frequency of claims litigated, 2) comparatively low cost of non-litigated settlements and/or 3) a high percentage of claims settled or closed without incurring direct costs to the compensation program.
Assessing Compliance with Approvals for Publication: Experience at the VA Pittsburgh Healthcare System

VA Pittsburgh Healthcare System
Ms. Tammy J. Capozzoli

**Topic:** Regulations and Guidelines

**Problem/Issue Statement**

The Veterans Health Administration expects its contributions to medical and scientific research to receive due credit and places the burden of that responsibility on its research investigators. As such, it is VA Pittsburgh Healthcare System (VAPHS) policy that all publications, presentations, media interviews, and professional activities pertaining to research conducted at, or under the auspices of the VAPHS acknowledge and publicly disclose VA support and affiliation, protect the privacy of patients, assure that the welfare of human and animal subjects was protected, and that the appropriate committee approval was obtained for all research involving human and animal subjects. Unauthorized research and requirements of acknowledgment is difficult to detect and assess. Although most facilities meet this requirement, the adherence to VHA Handbook 1200.19 and VAPHS Presentation of Research Results is often unknown.

**Description of Program/Research**

VAPHS Research and Development Office requires the following: 1. All investigators must initiate and document references to VA where either direct or indirect support for the research emanated from VA, either in the form of research funding, resources (e.g., facilities or patients), or as a result of the investigator’s full-time, part-time, or without compensation (WOC) employment status. 2. Acknowledge VA support and/or employment in all publications, presentations, media interviews, or professional activity where research results are being publicized, presented, recognized or discussed. 3. Submit all draft presentations or publications to the AO/ACOS, R&D. 4. Inform, either directly or through proxy, the VAPHS Research Office, at least 8 weeks (or as soon as possible), prior to the expected publication or presentation where research results are being publicized, presented, recognized, or discussed. 5. Acknowledgment of VA Research Support and of VA Employment. A quality assurance audit process was developed to evaluate the effectiveness of these requirements. Hypothesis Strong oversight and continuing education of investigators promotes compliance of the VHA requirements. Methods Publication Selection: A search of PubMed and Unbound Medline was conducted on all publications recognizing an affiliation with the VA Pittsburgh Healthcare System (VAPHS) was performed. Results were limited to manuscripts published since January 1, 2009 to December 31, 2009. Abstracts were reviewed to determine publication type. Letters, comments, editorials, case studies and review articles were eliminated from consideration. For all other publications, the full-text article was obtained online where possible. Institutional Review Board (IRB) and Research &Development Committee (R&D/C) records were reviewed to determine if appropriate committee approvals were obtained for the research protocols documented in the audited publications. Results There were 70 articles published from January 1, 2009 to December 31, 2009 with VA Pittsburgh listed as an affiliation. 13 of the 70 articles found were eliminated because they were published comments, editorials, case studies, review articles and letters. 2 articles were eliminated as the research was conducted and closed prior to employment with the VAPHS, although the investigator did acknowledge their VAPHS affiliation. Out of the remaining 55 articles, 51 were appropriately submitted according to the VAPHS Presentation of Research Results Policy and had secured the proper IRB or R&D/C approvals. Conclusions 1. Three of the articles reviewed appear to meet the definition of human subject research according to the 45 CFR 46.102(f). 2. Proper approval was obtained from the VAPHS IRB and R&D/C for 3 of the above publications and informed consent was prospectively sought from subjects when applicable. 3. The RCO was unable to determine if the research in 1 of the 4 articles was conducted at the VAPHS and therefore required R&D/C approval. The RCO was unable to locate R&D/C approval. 4. There is no evidence showing that VAPHS Research personnel or employees conducted human subject’s research activities without prior VAPHS IRB and R&D Committee approvals. 5. All four articles failed to adhere to the VAPHS Presentation of Research Results Policy. Specifically, VAPHS Presentation of Research Results Policy states that investigators must do the following: a. Submit all draft presentations or publications to the AO/ACOS, R&D. b. Inform, either directly or through proxy, the
VAPHS Research Office, at least 8 weeks (or as soon as possible), prior to the expected publication or presentation where research results are being publicized, presented, recognized, or discussed. 6. The RCO found no evidence of research published without proper IRB and R&D/C approvals. The results of the 2010 Annual Publication Audit report clearly reflect that compliance oversight in conjunction with education and training have increased awareness and compliance with the VAPHS Presentation of Research Results Policy.
Biobanking Considerations & the C-PROBE Paradigm  
June Insco; Crystal Gadegbeku, MD

**Topic:** Biobanking

**Problem/Issue Statement**

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 projects.

**Description of Program/Research**

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: o Storage—security, disaster plans (such as major power outages) o Personnel o Privacy and confidentiality o Informed consent Content of supporting documentation: o References to published articles o Regulations, accompanied by a brief overview of their implications o Resources to consider (such as data storage programs with robust security)

**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. We revised the drafts and posted the final checklists on the IRB website.

**Limitations**

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.
Biobanking for Dummies (and everyone else) - A Best Practices-based Approach to Training Development
M.D. Anderson Cancer Center
Nicole Sieffert, CCRC; Cindy Soto, BS; Sylvie Marcy, MHA, BSN

Topic: Training & Education

Problem/Issue Statement

Well annotated, preserved human tissues are the cornerstone of biological research. The cost and drive toward personalized medicine requires that newly-developed biorepositories develop evidence based practices while existing facilities refine procedures to meet the demands of an increasingly technical field. Unfortunately, few biobanking training programs exist, and fewer speak to the policies and practices of a particular environment or institution. The University of Texas M.D. Anderson Cancer Center (MDACC) has developed a Best Practices-based Tissue Repository Training Program for staff involved in specimen collection, processing, storage, use, distribution or destruction in an effort to address increasing biospecimen-related demands, and to optimize and standardize biospecimen quality.

Description of Program/Research

The goal of the MDACC Tissue Repository Best Practices Training Program is to introduce International Society of Biological and Environmental Repositories (ISBER) and National Cancer Institute (NCI) Best Practices for Biospecimen Resources to those directly involved in biobanking activities, and to various levels of the research community, including clinical staff. While the program’s ultimate purpose is to optimize and standardize biospecimen quality, its design encourages the protection of human subjects, collaboration between departments and institutions, and efficient resource use. The Tissue Repository Best Practices Training Program consists of four interactive, computer based modules; Sample Accrual, Sample Storage, Sample Events, and Informatics. Each module references key NCI and ISBER Best Practices and provides examples of their use in addition to helpful hints which are specific to MDACC policies and procedures. A quiz must be mastered for successful module completion. Web-based program access is available 24/7 to MDACC staff through the institution’s Education Center. Users may search by topic, title, category or date for available modules. Transcripts can be printed by individual learners, and monthly reports are generated for the purpose of tracking course completion. Program design was reviewed and approved by the MDACC Biospecimen Repository Advisory Committee, the Head of the Division of Pathology and Laboratory Medicine, and the Vice President of Clinical Research. Content and function were tested by the Director of the Office of Research Education and Regulatory Management in addition to MDACC Bank Directors, technicians, Laboratory Managers and clinical staff who found the program to be an excellent resource for training a broad range of personnel in various aspects of biospecimen-related function. The Program may be expanded at MDACC to meet the needs of specialty groups (i.e., organ-specific collections), and can serve as a model for any biospecimen repository with similar goals.
Breaking the Silence: Protecting Incapacitated Adults in Research
Julie Brintnall-Karabelas; Mary Ellen Cadman; Katherine Whorton; Carol Squires; Dave Wendler; Maryland Pao; Carol Squires; Dave Wendler

Topic: Special Populations

Problem/Issue Statement

Although research protections are required under the Department of Health and Human Services (DHHS), "the regulations are silent on the consent procedures specific to subjects with impaired decision-making capacity (Office of Human Research Protections, 2010)." Consequently, Institute Review Boards (IRBs) are faced with a challenging ethical responsibility when investigators seek to include incapacitated participants since federal regulations do require that "additional safeguards have been included in the study to protect the rights and welfare of all subjects that are likely to be vulnerable to coercion or undue influence (DHHS, 45 CFR 46, Subpart A)." The National Institutes of Health (NIH) is frequently challenged with the task of developing procedures and implementing the highest safeguards to protect vulnerable populations. When adults are unable to provide consent and an appropriate surrogate provides permission, human subjects protections which allow for ethical research participation can be included in protocols.

Description of Program/Research

The Human Subjects Protection Unit (HPSU) within the National Institute of Mental Health (NIMH) and the Bioethics Department (NIH) play an important role in the application and implementation of ethical standards within the Clinical Center. When a recent study which included adult males with a diagnosis of Fragile X Syndrome was developed, the need to create and implement safeguards took center stage. Given the inherent characteristics of such disorders, there are times when researcher’s can anticipate that participants may not be able to give consent. Consequently, unique protections can be incorporated into protocols and, following approval by the IRB, investigators can recruit participants in an ethical manner. This specific study included an array of human subject protections safeguards such as: • Consultation with the IRB • Consultation with Investigator's • Capacity Assessment of Adults • Assessment of the Appropriateness of a Surrogate • Consent Monitoring • Assent Monitoring • Behavioral Dissent Monitoring

Additional Information

When studies include incapacitated adult subjects, researchers have an important role in protecting their human rights. Research involving more than a minor increment over minimal risk with no prospect of benefit to the individual, requires that investigators ensure that participants are protected by the highest level of safeguards. The inclusion of unique procedures from the inception of a protocol to the final phases of research can serve to protect the participants and support the investigators in the advancement of science.
Capacity Development on Research Ethics: the experience of graduate students training in Nigeria
Ademola Ajuwon

**Topic:** International

**Problem/Issue Statement**

Capacity development in research ethics is important because it contributes to the protection of research participants. In Nigeria, access to training in research ethics is limited due to weak health, social, and economic infrastructure. Limited access to training is acute for Nigerian graduate students because research ethics is not included in their training curricular. As potential scientific and professional leaders of the future, training this population would have positive impact on the development of bioethics in the country. In 2005, a research ethics course, Ethics of Public Health Research and Practice, was introduced for graduate students of the Faculty of Public Health (FPH), University of Ibadan, Nigeria.

**Description of Program/Research**

The objective of the course is to empower students with knowledge and skills that would improve their capacity to conduct ethically acceptable research. This initiative is a direct outcome of the US-NIH funded Fogarty research ethics training program that the author received in 2003 from the Johns Hopkins School of Public Health. The course contents are history of research ethics, ethics guidelines, principles of ethics, Ethics Review Committees (ERC), informed consent, confidentiality, conflict of interest, and scientific misconduct. These contents are taught two hours weekly through lectures, group work, and discussion of case studies. Four sets making a total of 252 students have attended the course since its inception. Of the 252 who sat for the written examination for the course, 97.6% passed 2.4% did not. Students who attend 75% of the course and pass written examination are now being exempted from the online training required by the institutions’ ERC. Focus Group Discussion (FGD) held with 8 course attendees showed that competence on informed consent and confidentiality were the most helpful skills the students had applied to the researches they conducted since completing the course. Challenges and lessons learned A major challenge encountered when setting up the course was getting a time suitable for all students of the FPH who were to take it. This was resolved by teaching the course at 4-6pm when many students may be tired for the day. The teacher keeps the students ‘awake’ by making the class interactive. The contents most difficult to teach are the international guidelines which many students perceive as being too voluminous.

**Additional Information**

The author’s initial Fogarty training has produced multiplier effects on capacity development. It is feasible to develop a context-specific training program on research ethics in a developing country. The training for graduate students has addressed a previously unmet need for capacity development in research ethics in a major Nigerian university.
CDC's Human Research Protections Program; The Delegation of Research vs. Non-Research Determinations to CDC's National Centers

Centers for Disease Control and Prevention (CDC)

Natalie Brown, MPH; Denise Marshall, BS; Constance M. Bonds, MPA, CIP; LaShonda Roberson, MPH; Barbara DeCausey, MPH, MBA

Topic: IRB Operations

Problem/Issue Statement

Centers for Disease Control and Prevention (CDC) investigators are engaged in many research and non-research activities throughout the world. It is agency policy that all activities are reviewed for applicability of 45 CFR 46. This abstract will briefly describe one of the many processes that aids the CDC Human Research Protections Program (HRPP) in protecting the rights and welfare of those who participate in CDC sponsored public health research.

Description of Program/Research:

CDC's HRPP is comprised of 5 key domains responsible for ensuring human research protections: CDC Investigators, Associate Directors for Science (ADSs) and Human Subjects Contacts (HSCs), Institutional Review Board administrative staff (IRB Administrators), IRBs, and the Human Research Protection Office (HRPO) Chief. HRPO facilitates the work of seven distinct IRBs and provides assistance and training for CDC staff engaged in research involving human participants.

Locus of Responsibility regarding Research vs. Non-Research Determinations:

Documenting the review of activities and rendering research versus non-research determinations is a responsibility that has been delegated to each CDC National Center (NC). Within each NC is a HSC who works in collaboration with the ADS in rendering research versus non-research determinations for each activity. Classifying some public health activities as research or non-research can be difficult which may stem from the fact that 45 CFR 46 does not directly address many public health related activities. Once a research determination has been rendered, the HSC and ADS also determines if the research activity involves human subjects. All non-research and non-human subjects research determinations are documented within each NC, whereas all projects determined to be research involving human subjects are submitted electronically to HRPO for processing and IRB review.

Impact on the CDC Human Research Protection Office:

One of the key roles of HRPO is to support each NC by providing expertise, guidance and oversight related to 45 CFR 46. CDC has 13 NC’s that conduct numerous public health activities that cover a wide range of topic areas. CDC ADSs are knowledgeable regarding the emerging trends, priorities, and challenges related to the science within their purview. The collective review and determination made by the ADS and HSC for all public health activities facilitates the CDC HRPP in protecting the rights and welfare of those who participate in CDC sponsored trials. In addition, frequent consultation between NC ADS, HSC and HRPO staff occurs for important issues or dilemmas in rendering research versus non-research determinations. HRPO consists of 5 IRB Administrators, 1 Lead IRB Administrator, 1 Chief and 1 Program Operations Assistant who all assist in the management of nearly 1000 active research protocols and the operation of seven distinct IRB’s. Duties of HRPO staff also include but are not limited to: determining expedited or convened review of submitted protocols; assigning primary and secondary reviewers to research protocols; returning IRB reports and actions to HSCs and CDC investigators; issuing suspensions and terminations of research protocols; coordination of reliance agreements and appropriate training for IRB members and HSCs.

Suggestions for the Future:

HRPO staff will continue to serve as a resource for providing expertise and guidance to NC staff on an as needed basis. Future discussions are planned with the NC staff to highlight HRPO services and inquire as to what types of additional human subjects protections guidance and training they would like provided. Special emphasis may be given to international research activities conducted by CDC.

Suggestions for Implementation at Other Sites:

This method of operation provides timely, convenient, consistent and localized human subjects support to investigators within each of the NCs. Other large Federal Agencies that
conduct a wide range of research and non-research activities may find this process of delegation beneficial for their institutions.
Children’s Oncology Group and the IRB: Audit Preparation, Involvement and Action
Rhonda M. Pisk; Kristina Kinard; Linda Grigsby

**Topic:** Special Populations

**Problem/Issue Statement**

In May of 2010 Children’s Oncology Group (COG) conducted a programmatic audit of the pediatric oncology research program at Children’s Hospital Central California (CHCC). COG audits occur every three years and during this current audit period the institution integrated the National Cancer Institute, Central Institutional Review Board (CIRB) process in combination with local IRB review. We will discuss the involvement of the IRB in the preparation, facilitation and follow-up of a COG audit.

**Description of Program/Research**

CHCC IRB currently oversees 97 COG protocols. A cooperative agreement was established with the CIRB in 2006. At that time, policies and procedures were created to establish local accountability for facilitated review and management of CIRB studies. As of May 2010, 86 COG protocols are primarily reviewed by CIRB prior to a local facilitated review at our institution. In collaboration with the pediatric oncology research program at our hospital, the IRB was directly involved in the COG audit preparation. The Regulatory Compliance Coordinator conducted a complete pre-audit of all participant informed consent documentation (ICD). This process allowed us to identify a need for reviewing signed ICD in order to ensure current and ongoing compliance with all federal, state and institutional guidelines. Required elements, such as expiration dates, short forms, California Bill of Rights, complete signatures, and participant assents, were incorporated into a ICD review form that pediatric oncology clinical research associates (CRA) will utilize in ongoing efforts to manage the informed consent process. The COG audit included an IRB portion that covered protocol management and review as well as informed consent templates. The IRB was responsible for submitting approval letters (or facilitated review forms, if CIRB study) for the initial protocol approval, amendments, continuing reviews and study action letters on nine protocols. Current informed consent templates for thirteen studies were submitted for review. Our electronic document approval and storage process efficiently facilitated the retrieval and submission of the required documentation. During the audit, IRB staff was on hand to answer all inquiries and provide requested documentation. Supporting IRB documents were available remotely through shared network folders with controlled user access, limited to IRB and pediatric oncology research personnel. In compliance with institutional downtime procedures, paper copies of all IRB documentation is maintained by the IRB office. Our IRB policies and procedures were instrumental in achieving a COG IRB audit with no findings. As an outcome of the COG audit, the IRB collaborated with pediatric oncology clinical research personnel to establish a preventative action plan. IRB personnel will monitor new informed consent documentation weekly. The Regulatory Compliance Coordinator will conduct a monthly audit of a random study participant chart for protocol and regulatory compliance. Monthly audits will include CRAs, physicians and nurses in order to capitalize on educational reinforcement for process improvement and quality assurance. The methodology presented can be used by a variety of IRB programs to facilitate successful COG audits, as well as inspection by other regulatory agencies.
Clinical Research Education for Bedside Nurses  
*Clinical & Translational Science Institute (CTSI) / University of Pittsburgh*  
Jane Alexander; Mary Fisher; Patricia Lasher

**Topic:** Research education

**Problem/Issue Statement**

Education in clinical research and human subject protections has not historically been available to health professionals who are not study staff but who interact with and perform research interventions on research participants in their care. Providing this education to health professionals to enhance participant safety and research integrity is a CTSI initiative. Because of the intensive interaction between bedside nurses and their patients, bedside nurses were selected as the first health profession to be provided this education. Objectives include determining educational needs, stressing the important role of bedside nurses in the research community and providing avenues for obtaining education with CEUs.

**Description of Program/Research**

To respect the diverse schedules and organization of nurses across hospitals, a multi-prong approach was undertaken. CEUs were granted whenever possible. The program currently includes: slides welcoming nurses to the academic medical center research community during their orientation; a presentation of clinical research process, human subject protections and practical hands-on advice from a research nurse in a Clinical & Translational Research Center; webcast of the presentation; e-mail blast directly to nurses with resolution of research dilemmas at bedside; on-line module for existing nursing education module program; planned repository of educational tools, e.g. glossary, available from nursing station computers. Over 300 nurses participated in the presentations and provided positive feedback and exposed problems that they had encountered, including the need for better communication with research staff, confusion about study status of their patients, procedures without physician orders and overall intimidation with the research process. Future plans include focus groups and survey to elicit concerns more formally, an advisory committee of nurses and researchers to explore resolution of issues and pre- and post-testing of presentation attendees. Outcome measures will include increase in attendee knowledge and decrease in unanticipated events in inpatient protocols. Once well-established for nurses, this program will be adapted for other health professionals who play a role in the care of research participants. Suggestions for implementation at other sites include soliciting support from nursing management early in the planning stage and collaborating with nurse educators who can provide opportunities for presentations and can establish continuing education credits for the nurses who participate. Presenters should be experienced in how clinical research is conducted, in human subject protection regulations and in managing the inpatient care of research participants.
Clinical Research Recruitment and the ReSPECT Registry

Boston University
Kimberly K. Russell-Lucas, MPH, CCRP; Yurerkis Montas, BA

**Topic:** Special Populations

**Problem/Issue Statement**

Changing public perception of clinical research and study participation among minorities is a challenge faced by all clinical research scientists. Experts assert that the goals of research are not well understood by the public and problems with communication persist among researchers and the public. These communication problems can be an obstacle to researchers in study recruitment. Furthermore, data showing declining participation of minorities in clinical research seems to support claims of "a lack of trust." However, mistrust may not be the only factor for this decline. The researchers' perception of "unwillingness" may cause further stigmatization of minority populations, and may suggest that minorities are not willing to "work on" improving their medical care due to laziness and apathy. In contrast, recruitment experts suggest that the main barrier to the participation of minorities lies in their "reduced likelihood of being invited to participate." An innovative approach to successful study recruitment has been developed at Boston University (BU). The ReSPECT Registry is a way to target, recruit, and enroll diverse populations into research studies. The registry was launched in February 2010, with the goal to recruit thousands (~600 as of May 2010). Recruitment is ongoing. The aim is to build research capacity by easily connecting BU researchers to individuals seeking to volunteer in clinical research studies.

**Description of Program/Research**

Individuals can join the registry in-person, over the internet using a secure application, or by telephone. Individuals are provided a two-page information sheet that describes the purpose of the registry. The accompanying survey asks for contact information, preferred contact method (phone, email, or mailings), and some personal health information (PHI). Investigators access the registry by providing selection criteria and IRB approval to use the registry. The registry team does an initial search of the registry, and then another search via the electronic medical records. The program will be evaluated on the number of participants enrolled, the number of participants matched to researchers, and the number of participants recruited to studies. As we are at the start-up phase of the program, many of the processes are still being developed. This program has great potential at Boston University to reduce expensive recruitment cost, and increase study enrollment. Research teams usually go through several steps to finally find eligible study subjects. The registry is an innovative approach that may enhance minority recruitment to research studies by engaging them efficiently and effectively through a method chosen by them.
Community Engagement Efforts at NIH: Examining Best Practices of to Bridge Community and Research Agendas
Carlos Pavao

**Topic:** Community Engagement

**Problem/Issue Statement**

Many federal agencies struggle in how to define community engagement and how that principle applies to their public health programs. This workshop will examine 13 values, strategies to operationalize each value, and potential outcomes from these strategies, in how to promote public participation.

**Description of Program/Research**

Community engagement in research can enhance communities’ ability to deal with their own health needs and address health disparities issues while ensuring that researchers understand community priorities. However, there are researchers who have limited understanding of and experience with effective methods of engaging communities. To meet the need for researcher training in community-engagement approaches, the National Institutes of Health (NIH) Director’s Council of Public Representatives developed definitions of “public participation” and “community engagement” and a community engagement framework that includes 13 values, strategies to operationalize each value, and potential outcomes from these strategies. This framework offers a tool that NIH and others can use to expand the cadre of researchers who are well prepared to create and sustain authentic community-academic research partnerships.
Community Engagement Strategies for Ethical Consideration in HIV Prevention Research
Dr Adedayo Adeyemi; Dr Olubunmi Fakunle; Dr Oluseyi Adesola; Oluyemisi Olaogun

Topic: International

Problem/Issue Statement
Background: Ethical consideration and community engagement are vital for successful implementation of HIV prevention initiatives in Nigeria. There have been various advocacy programs to promote community engagement and ethics, and strengthen HIV prevention priorities in Nigeria. This is important towards the implementation of national HIV research priority agenda. Similarly, the advocacy will promote community understanding of the benefits of HIV research and the roles of community in research. Research Question: How can community engagement strategies for ethical consideration in HIV prevention research be promoted?

Description of the Research

Methods
There was a participatory stakeholder-driven workshop in February 2010 in Abuja Nigeria with consultations on community engagement, ethics and HIV prevention initiatives towards strengthening HIV research in Nigeria. Also, it involved the use of available and accessible qualitative, behavioral and programmatic reports to assess community engagement in HIV research and prevention.

Results
The workshop stakeholders identified need to expand ethical issues as an important component in HIV prevention programs and researches. Additionally, the stakeholders identified the following: the need to make community engagement a high priority in HIV prevention research; strengthen existing HIV activities with meaningful dialogues and advocacy for ethics; create enabling environment for community engagement; partner with communities; form local and international collaborations that will benefit communities; ensure community-oriented integration of HIV prevention efforts; and finally, the need to support innovative strategies of community involvement in HIV prevention efforts.

Conclusions
At the end of the workshop, the stakeholders came up with recommendations and plan to monitor and evaluate ethical issues and community engagement in HIV research. Stakeholders advocated for the need to support community awareness and promote good community practice in HIV research. There is the need to build capacity of community advocates; establish community networks and make community engagement an important aspect in the comprehensive HIV prevention agenda. Limitations: Participants were not represented from all the states of Nigeria and the need to ensure national representation in subsequent workshops. Next steps: There is a need for regular advocacy for ethics and community engagement in all the six geo-political zones of Nigeria to promote ethical issues and community involvement.
Compliance with Flexibility: A Successful Model for Protocol: Proposal Reviews

University of Pennsylvania School of Medicine
Christine E. Byrne; Dianna Bolt

Topic: Regulations and Guidelines

Problem/Issue Statement

45 CFR 46.103(f) requires that each application or proposal for HHS-supported human subject research be reviewed and approved by the Institutional Review Board (IRB). OHRP's corresponding guidance affirms that the IRB must ensure that the proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB. A near-miss in confirming the proposal to protocol review alerted us to the need for a more systematic approach to these comparisons. Our challenge was to work with researchers and sponsored projects contracts officers to develop a protocol: proposal comparison system that provided the former with flexibility and ease of use and the latter with timely assurance of review.

Description of Program/Research

LBNL is a Department of Energy laboratory managed by the University of California with a small, but robustly diverse HSPP. Contracts and proposals are funded by multiple sources; protocols range from surveys on home thermostat design through first-in-human injected radionuclide studies. Our two-person office also administers the IACUC and RDRC. Goals: Researchers needed a system that was easy to use and allowed one proposal to be linked to many protocols or many protocols to a single proposal. Contract officers needed timely verification that all human subjects work associated with a given proposal had approval. The IRB office needed a transparent process that would work for any funding agency and provide complete, accurate information. Process: A series of stakeholder workshops were held. After reaching agreement on ownership and responsibility, a Certification Request Form (CRF) and filing procedure were developed. The CRF leads researchers through the process of submitting the information needed; they sign the form to assure the accuracy of the information. Initial rollout was sponsored by the Institutional Official. Multiple forums for communicating the new policy, periodic reassessment and education tailored to address identified problem areas have been key. Outcomes: 18 months after rollout, compliance is good and stakeholder satisfaction appears high. Researchers find the process clear and response time fast. Contract officers find the system reliable. IRB members can perform needed reviews efficiently and only handle a proposal once; IRB staff no longer have to revise certifications repeatedly due to a lack of accurate information. Future development: Existing stakeholder buy-in and agreed-upon processes will make the Certification Request Form easy to automate in the Lab’s upcoming conversion to electronic proposal submissions and protocol reviews. Suggestions for Implementation at Other Sites: The stakeholder workshop approach to defining the process goals was a key factor in the success of the program.
Cooperative Subject Registry: A Method to Validate Volunteer Wash-Out Periods
Independent Data Integrator, LLC
Darran Boyer; Anita McSharry

**Topic:** Ethics and Risk Assessment

**Problem/Issue Statement**
Dual enrollment, or a subject enrolling in overlapping studies without meeting required protocol wash-out periods, is a serious problem facing the clinical trials landscape. Financial compensation received for participation can incentivize volunteers to risk their safety and dual enroll. This program will examine the use of a cooperative subject registry used by 5 neighboring sites to deter this problematic behavior.

**Description of Program/Research**

**Methods**
Five unaffiliated research sites within 200 miles agreed to participate in a web-based subject registry that collects limited subject identifiers and other data useful for preventing dual enrollment. Sites agreed to check the registry at the time of screening to monitor if a potential subject recently participated elsewhere, and prevent that subject from enrolling if necessary.

**Results**
The 5 sites have been able to improve their enrollment accuracy and the safety of their participants. After 6 months of use, the sites prevented numerous instances of dual enrollment- documenting over 50 instances where they prevented a subject from enrolling after identifying them as having received a dose within 30 days prior.

**Conclusions**
This program will suggest how other sites can implement a cooperative subject registry to improve their own enrollment accuracy as well as participant safety within their own research community. Also, this program will suggest how IRBs can understand the implementation of a cooperative subject registry, and steps that should be taken to ensure participant rights, safety, and confidentiality.
Creating a Cross-Country Collaboration
Aspire IRB
Pascale Susi; Currien MacDonald, MD, CIP

**Topic:** International

**Problem/Issue Statement**

US-Canadian studies are becoming increasingly common, especially considering the similarities between their populations. Being able to have a central IRB oversee these studies would add a level of efficiency not found in a cooperative agreement. Despite the similarities, there are distinctions, and a separate Canadian IRB (REB) is required. How could one combine the similarities, maintain the individual qualities, and logistically effect this creation?

**Description of Program/Research**

This poster will describe the process by which the creation of a REB-IRB interface managed by the administration of an existing IRB. It will first address the creation steps in sequence, showing the differences that are required to be maintained. It will also show a graphical representation of the overlapping functions, thereby highlighting the increase in efficiency.

**Additional Information**

Obstacles to continued implementation, as well as obstacles other institutions might learn from and improve upon will be addressed.
Creating an Appeals Process for IRB Decisions
Elizabeth B. Ripley; Monika Markowitz

Topic: IRB Operations

Problem/Issue Statement
IRB panels have autonomy to make decisions regarding human subject protections utilizing ethical principles, Federal regulations and institutional policies and guidelines. This autonomy should mitigate pressure on IRBs to make decisions which lessen the protection of human subjects. IRB panel determinations are not always accepted by investigators. Ideally, there is an open dialogue between investigators and the IRB where concerns can be voiced and modifications agreed upon. There has been little formal recourse for an investigator who disagrees with a full board, or expedited review, determination. Prompted by an actual case which could have benefited from a formal process, VCU has developed an appeals procedure to handle such situations. The new IRB Leadership and Enhancement Committee (ILEC), including representatives from the IRB leadership, investigators, community, and a patient advocate, was the vehicle for developing the formal IRB appeals process.

Description of Program/Research
Process for Appeal • If agreement cannot be reached informally, the investigator files an appeal outlining the decision(s) being appealed and providing supporting information. - The ORCE director serves as Chair for the Appeals Committee and a minimum of 6 individuals comprise the voting Committee members: Chairs/Vice Chairs from the uninvolved Panels, a non affiliate IRB member from a panel not involved with the review under appeal, the GCRC patient advocate, the Director of the ORSP, and a member selected by the investigator. - At the meeting, the Committee focuses on the unresolved issue(s), but will review the issue(s) in the context of the entire project. The investigator, involved IRB Chair and or panel members, and consultants will present the protocol and issue(s). - The Appeals Committee will reach a final decision by majority vote to either agree or disagree with the IRB panel decision. The following decisions and actions may be rendered: - Disagree with the decision of the IRB Panel and the protocol will be transferred to another IRB Panel for full review. - Agree with the decision of the IRB Panel. The committee will decide if transfer of the protocol to a new Panel for full review is indicated. - The minutes and Committee decision become a part of the IRB file for the protocol. - All decisions by the Appeals Committee are final and cannot be appealed. - Following the appeals process, the VCU ILEC will review the case and determine if changes in policy or education of IRB members and investigators is indicated.
Creating Awareness Of the Role Of Community Advisory Boards (CABs) in Research in a low-income, low resource setting: experiences from Zimbabwe

Medical Research Council of Zimbabwe (MRCZ) and European and Developing Countries Clinical Trials Partnership (EDCTP)

Mrs Melody E. Phiri-Shana; Sithembile Ruzario; Rutendo Zinyama-Gutsire; Resign Gunda

Topic: IRB Operations

Problem/Issue Statement

Community Advisory Boards are now seen as standard practice for clinical trials worldwide. Increasingly, researchers struggle with meaningful efforts to involve communities in research. CABs offer an opportunity to adopt an interaction prototype that enables researchers to anticipate and address the context in which communities understand risks/benefits, and individuals give consent. CABs provide a mechanism for community consultation that contributes to protecting communities and fostering meaningful research. Having realized that CABs in Zimbabwe lacked knowledge on their role in research, the MRCZ embarked on a training program. The aim was to properly educate and empower elected CAB members to become full partners in all research activities concerning the public within Zimbabwe by training them in Research Ethics.

Description of Program/Research

Using a grant from the EDCTP, in 2009, the MRCZ trained 120 CAB members. The MRCZ Monitoring and Training department with the assistance of the UZ-UCSF program, held consultative meetings with CAB Chairpersons to assess knowledge levels vis-à-vis the role of community representatives in research. It was during these meetings that a training schedule and modules were agreed on. Training Modules were simplified to ensure understanding and the modules were as follows:- Research in Zimbabwe, Understanding Research, Research Definitions, Role of CAB in Research and Case Studies. CAB members from Africa University, Chitungwiza, Epworth, Highfields, Harare City, and IMPPACT and ACTG studies were trained. The training revealed that there were gaps in the relations between researchers and CABs. This was exacerbated by both parties not respecting and appreciating each others' roles as well as by the fact that there are no set guidelines in Zimbabwe for establishing CABs. CABs understood that their involvement was on a voluntary basis, however it was realized that financial support for CAB activities was necessary and should be included in study budgets. However, there is a danger in that this could influence CAB members to alter their convictions or opinions of the research projects.

Additional Information

The training helped enhance the understanding of the role of CABs in research, as was evidenced by improved relationships between CAB members and researchers. Advocacy and sensitization meetings as well as trainings should be held to create an awareness of the opportunities for CABs to contribute to the research activities in their communities. Adequate funding should be made available as well as preparation for training, as the financial backing of CABs is necessary to ensure that the rights, safety and well being of participants is maintained. During training great care should be taken to ensure that the concepts are understandable, while at the same time making sure that the simplified ideas retain their scientific accuracy. Another important lesson we learnt was that the role of CAB members should be made clear to all those involved, as early as possible by putting in place frameworks/policies for engaging CABs in research. Should funds become available the MRCZ hopes to put in place a framework for engaging CABS in research in Zimbabwe as well as adapting modules for on-line training, thereby making training CAB members in Research Ethics accessible regionally and internationally.
Crowdsourcing for Continuous Improvement
Jim Pringnitz; Mindy Rice; Beth Kreofsky; Michelle Daiss; Helen O'Connor; Dr. Muhanad Hirzallah; Marcia Andresen-Reid; Gary Cseko; Dr. William Tremaine

**Topic:** QA/QI

**Problem/Issue Statement**

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. A majority of IRB submissions are returned to the research team for requested clarifications or changes prior to formal review. The amount of clarifications requested significantly impact resources, overall turnaround time and staff satisfaction.

**Description of Program/Research**

A team from the IRB attended Mayo Clinic's Quality Academy Teams Training with the specific goal of reducing the number of clarifications necessary. Several quality tools were learned including the DMAIC quality improvement method. DMAIC is an acronym for the five phases used in improving existing processes: Define, Measure, Analyze, Improve and Control. During the Improve phase, the team used an on-line, collaborative brainstorming tool (Launchpad software - Imaginatik) to crowdsourcing ideas or potential solutions. Crowdsourcing, a blend of the words “crowd” and “outsourcing”, was first coined by Jeff Howe in a June 2006 Wired article “The Rise of Crowdsourcing”. Problems or opportunities are broadcast to a group of solvers in the form of an open call for solutions, utilizing the collective intelligence of a larger group. The use of this method allowed solutions to be explored quickly and at less cost compared to other brainstorming methods. By listening to the crowd, the IRB gained voice of the customer insight from a wide range of experiences beyond those present within the project team.
Cultivating the Next Generation of Nurse Scientists: Partnering Academia and the IRB to Teach Undergraduate Nursing Students How to Move From Process Improvement to Research

University of New Mexico Health Sciences Center, College of Nursing and Human Research Protections Office
Dr. P.J. Woods; Linda Petree

**Topic:** QA/QI

**Problem/Issue Statement**

Baccalaureate Honors nursing student nurses are taught to use evidenced-based practice (EBP) in clinical care settings. This foundation often leads to students participating in quality improvement projects as their aim is to design interventions based on assessments of patient care processes and delivery care systems. While these are critical elements to learn, students were missing the knowledge and skills necessary to make a distinction between what constitutes application of knowledge in quality improvement and the generation of new knowledge founded in the nursing research process. There is often confusion for the students working within a health care entity about whether a proposed quality improvement project is subject to human research regulations and needs to undergo review by institutional review boards (IRBs) and many practicing nurses are fearful of research and IRBs and steer students away from research. As the majority of these Honors students plan to go on for masters or doctoral education, it is imperative they understand the difference between quality improvement and research so they begin building their research trajectory at the undergraduate level. In addition, clinicians and students often find they obtained results from a quality improvement project they now want to publish, but as the original intent of the project was not to “generalize” knowledge, they may have not engaged the IRB at the outset of the activity.

**Description of Program/Research**

**Program Overview:** A series of learning experiences that develop the necessary skills, knowledge and attitudes involved in identifying how quality improvement activities can be placed within the research context of IRB oversight were designed through collaboration between the College of Nursing and the Human Research Protections Office. This joint program established a series of learning activities for students that included: 1) taking the fear our of research and understanding human subject protection (didactic content related to steps in the research process and taking the IRB human protections training module as a course assignment); 2) clarifying the contributions of quality improvement activities and identifying challenges from the ethical viewpoint (using a decision tree to identify when quality improvement crosses over into research and collecting QA data in a way that protects human participants); 3) understanding the intent to generalize or not to generalize the data (through training/discussion with knowledgeable IRB staff in order to determine the threshold of when a QA activity becomes research); 4) bridging a quality improvement project into a research study (through creation of a simplified consent form or information sheet for quality improvement projects designed to teach students the required elements of informed consent); 5) disseminate information to enhance the learning process for future students (developed a quality improvement to research handbook with examples of consent forms for quantitative and qualitative quality improvement and research consent forms/information sheets, abstracts of projects and studies, examples of IRB template forms and completed submissions, protocols for development of quality improvement and research studies). Program

**Evaluation:** To evaluate the success of the program, we are collecting qualitative feedback from both students and clinicians in our partner health care entities related to the understanding of the differences between the quality improvement process and the research process. Consent forms, information sheets, abstracts and outlines are routinely reviewed by the IRB for content and clarity and feedback is provided to the students as to whether they are meeting the criteria for quality improvement, research, or both. In the first two years of the program, we had five groups of Honors students conduct quality improvement projects and four bridged their projects from quality improvement to research proposals. Of these four, three successfully obtained IRB approvals (one was for a study with a prison population) before they conducted their study and the fourth did a quality improvement project on PTSD in Emergency Room nurses went back and obtained IRB approval to publish their findings. In the past year, seven additional groups obtained IRB approvals and presented their research at the UNM Undergraduate Research Conference.
Symposium where three won academic awards with scores of 98 or higher out of 100. Suggestions for future program usage at your home institution Here at the UNM Health Sciences Center, other clinicians in Medicine, Pharmacy, Physical Therapy, etc. face the same issues related to performing quality improvement activities and conducting research, especially as it relates to results worthy of publication. We believe this project would be beneficial if it was taught in interdisciplinary format.

Suggestions for implementation at other sites: Creating the future nurse researchers for both the Doctorate of Nursing Practice (DNP) and PhDs is critical, especially in light of the aging faculty. We believe disseminating this program to other colleges of nursing is a first step in building our future researchers. We also see the benefit for clinicians working in health care entities who have this knowledge deficit as well.

Additional Information

Specific examples of quality improvement and research study projects will be presented to illustrate the program outcomes.
Curriculum Guide for Research Ethics Workshops for Countries in the Middle East
Prof. Azza S. Radwan; Henry Silverman, MD; Babiker Ahmed; Samar Ajeilat; Sumaia Al Fadil; Suhail Al-Amad; Hadir El-Dessouky; Ibrahim El Guindi; Mohamed El Guindi; Mustafa El-Nimeiri; Rana Muzaffar

Topic: Regulations and Guidelines

Problem/Issue Statement

Introduction: Since health research involves the participation of human subjects, it has become increasingly important to offer training in research ethics to those involved in the research endeavor. Such training helps ensure the ethical conduct of research and the protection of the rights and welfare of subjects. International organizations have made explicit recommendations encouraging researchers and members of research ethics committees (RECs) to complete a basic training program. To complement the use of these training programs, interactive workshops have the greatest potential to incorporate the most effective participatory learning styles. To be effective, such workshops should contain the appropriate content and learning styles geared towards the targeted audience. The Middle East Research Ethics Training Initiative (MERETI) has embraced the concept of multi-day workshops in research ethics targeted for different audiences.

Aim: We developed a curriculum training guide and associated learning materials to provide educational training in research ethics.

Description of Program/Research

We started by forming a Workshop Development Team and divided into two groups to develop curricula for members of research ethics committees and investigators. The team held discussions regarding the curriculum of multi-day workshops and then identified a set of core competencies defined as the “ability to perform a complex task or function” and consists of the requisite knowledge, skills, and attitudes to complete the specified task or function which state specifically what the learner should expect to learn (content area) and what the learner will be able to demonstrate upon completion of the program (behavioral action verb). Learning objectives may be classified into three domains: cognitive (knowledge and problem-solving skills), performance skills, and affective (attitudinal). The cognitive objectives, arranged from less to more complex, include knowledge, comprehension, application, analysis, synthesis, and evaluation. Emphases were placed on the higher-order cognitive objectives (e.g. apply, analyze, evaluate) in addition to those involving merely the acquisition of knowledge and understanding (e.g., identify, distinguish). The performance skills include the ability to write an informed consent form and to conduct its discussion with potential subjects without being misleading or coercive. Affective objectives refer to specific attitudes, values, beliefs, biases, emotions expected by learners to develop as a result of the instructional process.

Results: The team achieved consensus regarding the overall goal of workshops and on the basic core competencies needed to achieve this goal. These competencies for investigators and members of research ethics committees are in modular units incorporating the specific learning objectives of the core topics to achieve these core competencies as well as the corresponding instructional activities and learning materials to achieve the learning objectives. These learning materials can be obtained from the Workshop Committee Training website. Instructional activities applicable for the cognitive/knowledge learning objectives include lectures and articles for self-reading, whereas those to achieve objectives in the cognitive-problem solving domain (higher-order cognitive objectives) include the following: case studies, analysis of research protocols/informed consent documents, use of trigger videos to generate discussions. And those applicable for achieving performance skills include: role play involving the informed consent process; the writing of an informed consent form and mock REC review of protocols, while for the affective domain include: presentation of films. Many of these materials are relevant to the Middle East; for example, several articles were co-authored by investigators in the Middle East and several source documents are in Arabic. Many of the PowerPoint slide sets incorporate Arabic phrases and hence, would be suitable for an Arabic audience. Finally, many of the informed consent exercises, case studies, and research protocols are relevant to studies being performed in the Middle Eastern countries. Conclusion Workshops in research ethics have
been commonly used in developing countries as well as in developed countries. Such short-term training experiences can reach large audiences. We have suggested modular units and model agendas for such workshops that will ensure consistency in content as well as excellence across different developed workshops. The range of content included in the modules in the core curriculum should be sufficient for a broad range of audiences involved in research or the review of research. We expect that these workshop materials will provide a sustainable education resource for educators in research ethics.
Determining How to Support Research, Quality Improvement and Evidence-Based Practice in a Community Teaching Hospital
WellSpan Health
Melissa K. Schlenker; Tara L. Gross

Topic: Resource Utilization

Problem/Issue Statement
The Research Department and Institutional Review Board (IRB) resources at our community teaching hospital were being used to support quality improvement (QI) and evidence-based-practice (EBP) activities in addition to research. These competing demands, coupled with decreases in personnel and budget, strained the capabilities of the Research Department and IRB. A decision was made to hand off the non-research-related activities to the proper team for support.

Description of Program/Research

Methods
In the past, only resident and attending physicians used our services for research-related activities requiring IRB review and approval. As institutional officials based more operating decisions on the outcome of QI and EBP activities, additional staff members sought our technical assistance. Based on our interpretation of the Exemption Review regulations established by the Office of Human Research Protections (OHRP) many of these activities required exemption from review determinations. Since OHRP released new guidance on QI activities, the institution has established a new policy that QI activities do not require IRB determinations unless they contain elements of research or plan to disclose protected health information. This has led to a decrease in the IRB resources required for this process. We realized that a paradigm shift needed to occur within the institution to address the issue of providing technical support for non-research activities. To be successful we would need the support of Corporate Quality Management and Nursing Research leadership. A committee was formed and weekly meetings were held. As a result of these discussions, a flowchart was developed to determine the activity type and resources needed. This established which team provides technical assistance.

Results
These changes are in progress at our institution. Resource usage is being tracked by each group to determine if this shift will lead to a decrease in time and resources the Research Department spends support QI activities.

Conclusions
Many research departments and IRBs are working with limited resources and are under staffed because of the depressed economy and institutional funding cutbacks. While our institution’s resource support system may be unique because of our status as a community teaching hospital, we feel that our process to distinguish activity type and the proper resource utilization may be useful for other institutions.
Developing a Research Institute: Centralizing Regulatory Oversight and Encouraging Research Advancement at a Community Based Healthcare System

ProHealth Care
Tanya Carrillo; Dr. Michael McCrea; Laura Koch

**Topic:** Research Oversight Operations

**Problem/Issue Statement**

Research at non-academic, community-based healthcare organizations often receives minimal oversight and support; while investigator initiated projects are not strongly encouraged and resources are not readily available. With minimal regulatory oversight IRBs and other departments become the gatekeepers for research regulation. Executive leaders at ProHealth Care recognized the need and value of a department to oversee and advance research by providing services and oversight in a centralized function.

**Description of Program/Research**

**Human Research Protection Program (HRPP)** The HRPP ensures compliance with all applicable regulations and ethical guidelines for human research. The HRPP has adopted a model that emphasizes responsibility of all individuals in the organization, rather than focusing on IRB support staff. The HRPP is managed by one FTE who serves all roles included in a typical IRB office, and oversees dissemination of responsibilities to components of the HRPP.

**Grants and Contracts Program (G&C)** The G&C Program offers comprehensive services to investigators. The office is currently managed by one FTE who: Identifies funding sources and supports investigators; provides review, negotiation, approval, and execution of all clinical study agreements and grants; oversees research regulatory compliance; and monitors all research financial activity for the organization.

**Research Advancement** The research advancement component provides support throughout the research cycle in the areas of scientific advancement, research development, and research funding. From the “idea stage” investigators are guided though the research cycle and provided resources. The Research Advisory Council (RAC) provides assistance with project development. A scientific writer aids with grant writing and scientific publications. A biostatistician consults in the project development phase, as the research is conducted, and upon research completion with aggregation/analysis.

The program is evaluated by executive leadership, its staff, and its customers on an ongoing basis through open communication. The Research Institute staff meets on a weekly and quarterly basis, evaluating ongoing priorities and strategic planning to meet objectives. Staff also meets with its customers for feedback and to explore possibilities for improvement.

In the future, we plan to refine procedures to create further efficiency and collaboration between the HRPP and G&C.

Starting a program at an institution that already has departments serving these functions may pose challenges. Transparency and collaborative working relationships with customers is essential to success.
Elements of a Successful Informed Consent
Mary Ellen Cadman; Jean Murphy; Maryland Pao

Topic: Informed Consent

Problem/Issue Statement
The Human Subjects Protection Unit (HSPU) of the Office of the Clinical Director, Intramural Research Program, National Institute of Mental Health, (OCD, IRP, NIMH) monitors the informed consent discussion between investigators and prospective protocol participants for numerous studies in the research program of this and other Institutes in the Clinical Center of the National Institutes of Health. These protocols are required by the Institutional Review Board to be monitored by an independent observer because they involve subjects with potentially impaired decision-making or are greater than minimal risk for subjects. Over several years of monitoring studies conducted by different investigators, variations in the quality and style of the informed consent discussion have been observed. Usually a new investigator learns how to perform an informed consent discussion by observing another, more experienced, investigator. No formal educational tools are available in the IRP to teach this important skill so a video was developed by HSPU in which an investigator obtains informed consent from a prospective research subject.

Description of Program/Research
All of the required elements of informed consent are presented in a conversational style which encourages the participation of the subject. A narrator introduces the video, discusses the required elements, makes stylistic recommendations for investigators, and concludes with a summary of the important points. A pre and post test were developed based on the content of the video. Data will be presented on the scores of the research staff who completed these tests before and after watching the video. The average pretest score, post test score and the significance of the improvement between them will be presented. The video will be posted on the NIMH IRP OCD website and made available to all research staff, particularly new investigators coming into the Institute. It is anticipated that this training will be utilized throughout the NIH as an educational tool and could be utilized in other facilities where the training of new researchers is a priority.
Essential Regulatory Compliance Tools and Checklist for the documentation of the Informed Consent Process

U.T. M.D. Anderson Cancer Center

Martha J. Matza, MS CIM CIP; Laury D. Finn; Matthew Z. Lindblom, MS; Maria K. Mercado-Cooper

Topic: Informed Consent

Problem/Issue Statement

Investigators are required to meet Institutional Review Board (IRB) regulatory standards by providing the current IRB-approved informed consent to the participants in a human subject research study. The Code of Federal Regulations (CFR) 50.27 (a) states that informed consent shall be documented by the use of a written consent form approved by the IRB. Unless a waiver of authorization or a modified consent has been approved by the IRB, the investigator must follow a standard operating procedure to ensure the current IRB-approved informed consent is used during the consent process. This consent must be made available to the subject and made available for institutional or regulatory officials during the review of the study outcomes.

Description of Program/Research

Tools have been developed for use by any level of an organization to provide guidance and structure to document the informed consent process for Phase 0 through Phase IV clinical studies. These tools can be applied towards studies that involve any number of subjects. The set of guidance tools assist in the attempt to eliminate human errors when documenting the consent process of subjects during clinical study enrollment. They include a checklist of items for the investigator when preparing to discuss the intended research study with potential subjects. The checklist should include procedures to ensure that the most recent IRB-approved consent document is used during the consent process, points of discussion between the investigator and research subject, and steps for documenting the complete consent process. The procedure begins with the electronic or manual retrieval of the current consent document by the research staff or investigator. Points of discussion with the subject include the proposed investigational treatment, potential risks to the subject, potential benefits to the subject, and any alternate treatment options. The documentation guidance includes a checklist for the investigator, with points to include in the study entrance note of the medical record, confirmation that all signatures have been obtained and dated appropriately on the consent document, and confirmation that the final signed consent document is appropriately placed in the institutional medical record.

Additional Information

Suggestions: These guidance tools are provided to all investigators, along with an educational session. Periodically, an unbiased review of tool usage and an audit of the consent documentation should be completed. This strategy provides a mechanism for continuous improvement of consent documentation and helps to fulfill the regulatory requirements necessary for the protection of human research subjects.
Ethical Access to Patient Information for Research Purposes

University of Nebraska-Omaha; University of Nebraska Medical Center
Joseph S. Brown; Toby Schonfeld; Dr Bruce Gordon; Dr Jean Amoura

**Topic:** Regulations and Guidelines

**Problem/Issue Statement**

We argue that maintaining a patient's right to privacy is an essential factor in determining who has ethical access to patient information. Our thesis is that unfettered access to patient information for recruitment or screening for research violates a patient's privacy. This stands in contradiction to the preparatory research provision of HIPAA that permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. We argue that the only legitimate access that health care providers have to private information is through the authorization granted to them by patients to provide clinical care to them. Such access can be granted only by IRBs that have considered the risks of what is essentially a waiver of consent against the legitimate ends of those engaged in the research enterprise.

**Description of Program/Research**

An important implication is that several current research practices permitted without IRB review and in accordance with HIPAA would be unethical. For example: • Employing a research nurse or coordinator to screen patients' medical records for inclusion criteria would be illicit without patient consent • Partners of physicians who had no actual clinical interaction with the patient does not have ethical access to her information for research purposes • Health care providers' secretaries, while functioning in a legitimate capacity in a clinical context, would not be able to send letters about research participation if doing so would require them to acquire new private information about the patients

**Additional Information**

The rationale for limiting access to a patient’s information in the clinical context is that the patient reserves the right to authorize or not to authorize the release of his or her private health information beyond what is necessary for treatment, payment, or health care operations. If the proposed researcher already has a clinical relationship with the patient such that he or she has already had access to the patient's clinical information, no expansion of access to private health information is required in order for the researcher to screen the patient for inclusion or to strip identifiers. This is because there is no information leakage when information the individual already has is used for research. However, the potential of knowing this information in order to provide care (e.g. the ethical access of a partner who might use the information in order to care for the patient while on call) is not sufficient. We argue that access increases the scope of persons privy to private patient information solely for research purposes and is therefore unacceptable. This increased scope of access can subject patients to a variety of harms, ranging from social stigma to employment difficulties to the erosion of trust in the medical encounter. Therefore, based on the notion of maintaining patients’ privacy rights, only a researcher who has ethical access to a patient’s information for clinical purposes has ethical access to that patient’s information for identifying potential research subjects. Only IRBs should expand that access further.
In contemporary time, the aspirations of science and medical research or the need for scientific advancement are not only important but are urgent too. For example, research on preventive HIV vaccine. However, inherent lies are the danger that the wellbeing/rights of research participants may be compromised. This apprehension is intensified where research participants are particularly vulnerable for various reasons, such as their socioeconomic status, age, gender or educational level, e.g. African countries. Ideally, the ethical-legal framework operating in a country should aim to strike this balance between the goals of science and the rights and welfare of human beings, through legally binding structures and processes to regulate research in accordance with uniformly accepted norms and standards.

The work presents a review of existing ethical-legal and regulatory framework in Africa. The objective includes determining whether the countries in the continent have adequate laws, ethical guidelines and policies in place to regulate human research. The countries covered in broad spectrum- Botswana, Egypt, Ethiopia, Gambia, Kenya, Malawi, Nigeria, South Africa, Sudan, Tanzania, Uganda and Zimbabwe. It reviews the existence of key organizations, legislation, regulations and national specific guidelines or standard operating procedures (SOPs) concerning ethics in general and in: -Genetic research-clinical research with particular ref. of HIV vaccine research - Biomedical research with human participants -Drugs - Human Rights Law -Monitoring and enforcement mechanism It further reflects on some specific challenges- general in the continent: A. Regulatory challenges B. Inequities in research priorities.. - Health research priorities?? C. Ethical challenges D. The rights of participants It further highlights the amplified pace of research ethics in the continent. It places of interest: -Increased research activities in the field of health science; - Increased advocacy and awareness on the requirement of ethical –legal framework parallel to increased funding for R&D on the research ethics; - Increased “non- traditional” players and emerging partnerships; - Increased pressure on ethical and regulatory mechanisms

To create a gateway of information for further research ; to share and disseminate the information for future ground work and alliances for the advancement of interest of a larger community in the continent.

The findings indicate that most of the countries are showing signs of moving towards a ‘cautious regulatory’ model of ethical-legal regulatory review of research. However, in most countries the structures, processes and standards are set out in policy and guidelines, rather than in law as is recommended by this model. Additionally, all most all of the countries have a system of administrative review to regulate the ethical review of research, generally through a system of research ethics committees (RECs). There are still limited research-specific laws setting out norms and standards relating to how research is regulated, what is considered to be lawful research, and what the rights of research participants are. Most of the countries do have detailed norms and standards for research; however these are still contained primarily in ethical guidelines, and do not have the force of law.

Despite investments in the health sector, the health system remains weak as evidenced by lack of coordination, fragmentation of services, dearth of resources, including drug and supplies, inadequate and decaying infrastructure, inequity in resource distribution and access to care and very deplorable quality of care. Lack of clarity of roles and responsibilities among the different levels of government has compounded the situation. The absence of national
health legislations in most African countries to back up the health policies/guidelines has been a fundamental weakness which needed to be tackled directly. This limitation implies that there is no health legislation describing the national health system and defining the roles and responsibilities of the three tiers of government and other stakeholders including researchers in the system. - To present in a seminar/ethics training workshops in the University -to publish in internationally acclaimed journal
Exploring New Sources of Funding to Support the HRPP: Cancer Center Coordinator
John Heldens

**Topic:** IRB Operations

**Problem/Issue Statement**

Due to the State of California's budget crisis, funding for many University of California programs, including the UCSF HRPP was and continues to be reduced. The Helen Diller Comprehensive Cancer Center was looking to ramp up clinical trials, particularly Phase I trials in partnership with a new UCSF CTSI-supported Phase I Clinical Research Center. The Cancer Center supported the work of the HRPP and was willing to contribute funding to make sure studies were reviewed in a timely fashion. However, the Cancer Center wanted to make sure the additional funding went to the efficient review of Cancer Center clinical research.

**Description of Program/Research**

The Cancer Center provided funding for a new Full Time Employee (FTE) within HRPP, a Cancer Center Coordinator. The Cancer Center participated in writing the job description and in the interview process, but the final hiring decision was made by HRPP. The Cancer Center Coordinator reports to an IRB manager within the HRPP. The Cancer Center Coordinator performs very similar work to other coordinators within HRPP, such as pre-screening, assigning studies for review, attending IRB meetings, drafting correspondence following IRB meetings, and screening investigators' responses to that correspondence. The UCSF HRPP received more studies from the Cancer Center than one Coordinator can review, so the Cancer Center Coordinator meets regularly with Cancer Center Managers to help prioritize submissions. The Cancer Center Coordinator’s primary focus is on new clinical trials, and rarely works on changes to approved research or on continuing review. The Cancer Center Coordinator also coordinates NCI CIRB submissions and facilitated reviews for HRPP. The primary outcome was the date the study was first submitted to the HRPP to the date of first approval. The success of this program has resulted in additional funding from the UCSF CTSI to support studies taking place on one of the Clinical Research Centers. This mechanism of funding could work with any research unit with a large volume of studies.

**Additional Information**

The person hired as Cancer Center Coordinator is very knowledgeable and before coming to this position had about 8 years of experience as an oncology clinical trial coordinator, and worked for a period of time within the HRPP Quality Improvement Unit.
Getting Started on the Right Foot: Study Start-up Consultations
Yale University
Tracy Rightmer, JD; Sandra Alfano, PharmD; Kathleen Uscinski, MBA

**Topic**: Post Approval Monitoring

**Problem/Issue Statement**

Most human subject protection monitoring programs are aimed at identifying non-compliance after the fact. Audits and Quality Improvement (QI) activities are effective in catching issues once they’ve already occurred. Aside from broad educational initiatives, there are limited mechanisms for addressing or pre-empting potential non-compliance before it becomes a problem.

An innovative service offered by the Yale University Human Research Protection Program (HRPP) Compliance Program is the Yale Study Start-up Consultation program. The program was developed to help investigators navigate the myriad rules and regulations surrounding the design and conduct of human subjects research before the study begins enrollment. The intent is to ensure that research teams have the proper information, tools, and understanding to implement appropriate processes, oversight and data documentation techniques. The goal is to help new investigators avoid many of the common mistakes that might lead to non-compliance, and to start the team off ‘on the right foot’. The program was especially designed to target new researchers or researchers new to Yale but has been requested and well used by experienced researchers as well.

**Intended Outcome**

The intended outcome of this service is to ensure protection of human subjects and to foster compliance with human subjects protection policies and regulations via an individualized and protocol specific outreach with the investigative community.

**Description of Program/Research**

Prior to the start-up visit, the HRPP staff member reviews the protocol and consent documents to gain an understanding of the study, the data documentation needs and identify areas of potential non-compliance. A visit is then scheduled, which generally lasts about 1-2 hours. This visit focuses on common investigator concerns, investigator responsibilities related to the conduct of the study, subject interactions, communication with the IRB and sponsors, study specific documentation and retention requirements and University policies and applicable regulations as they relate to the particular study. Research team members have the opportunity to ask questions and discuss study specific issues prior to actually starting the project to help ensure an efficient study process which is compliant with applicable regulations and IRB expectations. The HRPP staff member may provide templates and checklists for use by study staff and may aid in the design of case report forms or source documents. The service has been used both proactively by investigators wishing to ensure a solid foundation when commencing their study and as a corrective measure for investigators who have demonstrated a need for closer oversight.

**Evaluation**

The start-up program is evaluated by survey. After a visit is conducted the participating research team is sent an evaluation form and asked to provide feedback if they wish. Informal feedback has been very positive and although the program is new, it is quickly being recognized as a positive effort, and requests for the service have been steadily increasing each quarter.

**Suggestions for future implementation at home institution and for implementation at other sites**

The key to success for this program is to get the word out to investigators. Most seem eager to utilize the service once they know of it. Plans are in place to use a newsletter and email announcement as well as discussing the service at other educational sessions and departmental meetings. The start-up consultation service is versatile and
can be implemented easily at other institutions. Currently the service is being provided as part of a portfolio of compliance activities performed by one full-time employee and one part-time employee, who conduct approximately 4 start-up consultations per quarter or as requested. Institutions wishing to offer this service should assess the likely demand against the resources. Since consultation visits are generally short it should be feasible to implement the program with minimal staff.

**Additional Information**

The service is offered on the Yale HRPP website (http://www.yale.edu/hrpp/) where investigators can request a consultation. Checklists, forms and templates are also available on the website for researchers to use and modify as necessary.
Highlighting the Role of IRB Administrators in Peru: The US Naval Medical Research Center Detachment Experience

US NMRC - DoD Navy
Zoe Moran; John W. Sanders; A. Roxana Lescano

Topic: IRB Operations

Problem/Issue Statement

The NMRC Research Administration Program (RAP) has offered an annual workshop for IRB Administrators since 2006, and in 2009 we were asked about the possibility of an on-site formal training program for IRB Administrators and IRB Secretaries. A training program was designed for this group and in 15 months it has trained 4 Peruvian professionals in this area of expertise.

Description of Program/Research

This training program involves 12 weekly sessions of 4 hours for a period 03 months at the NMRC RAP. The program topics included conducting pre-review of research study submissions to determine completeness and accuracy, communication with investigators and IRB members, use of IRB forms and checklists, creation of IRB agenda and meeting minutes, recordkeeping in electronic and physical files, reviewing IRB policies and procedures, developing Standard Operating Procedures (SOPs), providing training to IRB members and investigators, managing infrastructural and administrative supply needs for IRB meetings, compliance of national and international regulations, among others. Prior to the training, RAP requested a copy of each IRB’s SOPs in order to customize the training according to their practice. An anonymous survey was administered to the trainees to assess whether their needs had been met and to ask for comments. According to this survey, they all appreciated the duration of the training and the personalized method used. They believed that the most useful training topics could be summarized into seven areas:

1) how to conduct a pre-review of a protocol submission;
2) creating protocol databases and logs;
3) drafting IRB agenda and meeting minutes;
4) communicating with investigators and IRB members;
5) use of IRB submission forms; 6) how to review a consent form and,
6) drafting SOPs.

They reported that they have implemented their practices with the tools provided. For example, the creation and use of protocol databases and logs allowed them to follow up on IRB actions and protocols more accurately; the use of IRB submission forms and checklists allowed them more efficient control and management of IRB review related documentation; the guidelines on how to draft the IRB agenda and minutes improved the organization and conduct of IRB meetings; and in general they considered that the training received has positively impacted their daily work within the IRB, with the IRB members and with the investigators. This unique training program offers important possibilities for Peruvian IRB Administrators and/or IRB Administrative Support staff since limited or no training exists locally. Also, it was a first step and we hope to work with national and international organizations to develop a local standard and certification.
How to Get your Staff Ready to go from Paper to Electronic Submission
Carlotta M. Rodriguez; Donna Hoagland

**Topic:** IRB Operations

**Problem/Issue Statement**
At our institution, prior to 2010, all IRB submissions were completed on paper. Due to a request from our research community, the institution purchased a vendor software package in 2007, that will allow our investigators to submit electronically as well as allow our IRB members to review on-line. For the past three years, we have worked together to ensure that we are utilizing all the features of the system to its fullest potential. For example, the IRB has a multitude of submission forms; we have worked to ensure that Smart Form technology was being utilized so our investigators do not have to complete sections that are not applicable to their research study.

**Description of Program/Research**
This has required the IRB Office Staff to undergo intense, hands-on training. We found that sitting down and conducting discussions wasn’t working, therefore, we started to utilize a teach the teacher method that required the IRB Office staff to assume various roles that they each had to play as well as what was expected from them. For example, each of the staff had to assume the role of a principal investigator and submit a new IRB study. Each staff person was graded on the assignment as well as they were each required to provide feedback on the use of the system. We worked to ensure that our staff was prepared to answer any and all questions pertaining to the submission process and clearly understand what can be done in each of the roles. The Stratford campus is scheduled to go live with the system in the summer of 2010, Newark, Fall 2010 and the New Brunswick campus January 2011.
Impact of Teleworking on Productivity, Work-Life Balance, and Job Satisfaction

Vanderbilt University Human Research Protection Program
Laura Greene, RN, CCRP; Emily Foster, BA, CIP

Topic: IRB Operations

Problem/Issue Statement

Our society has changed radically over the past half-century with families increasingly relying on more than one earner for household support. Because of these changes, numerous workers face conflicts between their work and their personal lives, but they also inspire a need and desire for more flexibility in the workplace. One option to allow for flexibility is telecommuting. Other terms for this arrangement include e-commuting, e-work, working from home, or teleworking. This work option is a regular, routine work arrangement that allows the staff member to fulfill his/her primary job responsibility at a location other than his/her work site, such as at home.

The expected outcome of implementing a telework program for staff members at the Vanderbilt Human Research Protections Program (VHRPP) included an increase in self reported perceived productivity, perceived performance levels (which differs from productivity in that it is not output oriented), an increase in employee satisfaction with their work/life balance, and an increase in reported job satisfaction. It was also anticipated as a secondary outcome that this program would increase actual productivity.

Description of Program/Research

The telework program was created to offer staff members an alternative work arrangement. The program was offered to staff members who demonstrated self-discipline and self-motivation as well as the ability to work alone and showed proficiency with independent problem solving. These qualities were validated in performance evaluations. An Alternative Work Arrangement Agreement was created to define teleworking parameters. Implementation began with staff members teleworking from a workstation other than a Vanderbilt University facility for one day a week. Staff members collaborated with supervisors and co-workers to create a teleworking schedule that accommodated the needs of the department and the teleworker. A baseline was established prior to implementation of the program utilizing an alternative work arrangement survey to assess feasibility, perceived productivity, perceived performance, job satisfaction, and perception of work/life balance. The program was implemented for a period of 3 months. The program was evaluated with a post alternative work arrangement survey. The surveys were administered through a program called Research Electronic Data Capture which is a secure, web-based application designed exclusively to support data capture for research studies. The secondary outcome was examined by analyzing productivity dashboards and “Measures of Success” which are available to VHRPP staff members. The future of the program may allow for an increase in teleworking days. This program could potentially serve as a model for other institutions who wish to offer innovative opportunities to their staff members.
Implementation and Evaluation of a Quality Assurance Process
Vanderbilt University
Barbara Gibson; LuEllen Davie

Topic: QA/QI

Problem/Issue Statement

The cost to a participant of taking part in a research study is a required element of informed consent. The Vanderbilt University Human Research Protection Program observed a need for improvement in the content of the informed consent document for research cost exposure. Specifically, there was the potential for research participants to not understand their risk with regard to the cost of taking part in a research study. Therefore, a quality assurance process was developed and implemented to better define the financial responsibility for research procedures in the informed consent document.

Description of Program/Research

The quality assurance process involves assessment of the content of the informed consent document compared to the billing plan submitted to the Department of Finance. The consent document is reviewed for billing intent of research and routine care procedures. Predetermined criteria measure if the content of the consent form is adequate with regard to billing and financial responsibility. In addition to the billing plan and consent document, other pertinent documents such as the protocol, the contract, and the grant are reviewed. After a review of the documents is complete, a detailed itemized summary of audit findings is created with suggestions for improving the clarity and consistency of the study documents. Audit findings are communicated to the Health Science Teams by sending the summary via a database specifically created for this purpose. The Teams then review the summary and address the findings with the researcher.

The quality assurance process goals were to:
- Improve content in the informed consent document for research cost exposure
- Promote consistency across study documents for research procedures and billing intent of these procedures
- Gather data for targeted education for quality improvement
- Institute quality improvement processes by developing tools to assist with the review of study documents and to provide real time feedback.

The primary method used for measuring improvement was to audit the percent of studies requiring clarification for research procedures and billing intent. The 3-month period prior to implementation of quality improvement processes was compared with the 3-month period after implementing quality improvement processes. There was a 26% improvement in capturing processes and content, meaning there was no need for revisions or clarifications in either the consent form or billing plan, and processes were followed and completed; there was an 8% improvement in accurately capturing research procedures in the consent form, meaning there were no regulatory concerns; and there was a 1% decrease in appropriately capturing the billing intent for procedures described in the protocol (routine care and research), meaning there was a discrepancy between the consent form content and the billing plan. Future plans include collaborating with other regulatory departments to provide education to the research community. Additionally, we plan to refine the database to automatically generate reports based on specific parameters, providing real time feedback. We have found this quality assurance process adds value to our program. Incorporating this process at other institutions will result in improved content of the informed consent document.
Implementation of a Process for Clinical Trials Registration in a Public Registry, ClinicalTrials.gov

U.T. M.D. Anderson Cancer Center
Laury D. Finn; Michelle Morgan; Martha J. Matza, MS CIM CIP

Topic: Regulations and Guidelines

Problem/Issue Statement

Food and Drug Administration Modernization Act of 1997 addressed and established a public clinical trials registry listing research trials available for a particular disease or condition, specific treatments, and study locations in everyday language to ensure prospective research subjects are able to make informed choices while comparing benefits and risks of taking part in medical research trials. U.S. Public Law 110-85 defined further mandates with basic results and adverse event reporting.

Description of Program/Research

Research investigators on clinical research studies are required by this law to register applicable clinical or device trials in a publicly available database. The National Institutes of Health (NIH) through the National Library of Medicine (NLM) have implemented a web-based application, ClinicalTrials.gov, as the public registry. Research investigators are required to register study details in the database including basic results information and adverse event reporting. Gathering needed information on applicable clinical trials internally and interdepartmentally as well as maintaining data integrity reported in the database in a systematic method within deadlines mandated by public law is an ongoing challenge.

Description of the Program

A process has been developed for ClinicalTrials.gov registration that defines trials requiring registration, maintenance and updates of study information of registered trials within the public law’s requirements. Initial questions are used to determine if the trials are applicable for registration, phase of trial, and determination of trial sponsor. Based upon answers, the trial is registered in ClinicalTrials.gov by the institution, sponsor, or other entity. Study information entered is emailed to the study principle investigator as an attached file including a registration receipt. The principle investigator can provide feedback on proposed registration information. Once study information is posted on ClinicalTrials.gov, the registration number (NCT#), provider of information, and responsible party are documented. The registration process is complete and the NCT# is available to faculty and staff via protocol reports.

Additional Information

Suggestions

Institutions should proactively develop a program using dedicated staff for trial registrations, most importantly for basic results entry and adverse event reporting. Resources should be available toward completing study entry, registration, ongoing updates of information and inclusion of additional or revised information as new required fields are implemented. Registration of clinical trials in a public registry empowers people who are facing life-threatening illnesses to make knowledge-based decisions and fosters communication between research subjects and their medical providers.
Implementation of Egyptian Network of Research Ethics Committees (ENREC)
Prof. Azza S. Radwan; Dr Hany S. Sleem, MD; Prof. Henry Silverman, M.D.

**Topic:** International

**Problem/Issue Statement**

In response to an increase in health research and a recent accreditation requirement for universities, Egypt has established many research ethics committees (RECs) during the last few years. As different RECs develop in Egypt, the lack of interaction among them could lead to inconsistent practices in the review of research. Although uniformity could be fostered by national research regulations, these are not forthcoming. Accordingly, there is a need to utilize novel networking tools to augment sharing of information resources, review strategies, policies, and intellectual resources that will lead to enhanced processes for protecting research subjects.

**Aim**

To enhance the coordination between RECs, we aim to establish a Virtual Collaboration Network (VCN) of RECs in Egypt in order to enhance their efficiency and consistency in the review of research.

**Description of Program/Research**

The establishment of a network requires several steps and includes: a) distribution of a survey to obtain background information on the needs and existing resources of currently functioning RECs in Egypt; and b) the implementation of two internet tools: a web conferencing system and an internet Learner Management System to foster communication and sharing of educational resources, respectively. Results: At the present time, the following has been performed: 1) We distributed surveys to 16 RECs and 11 completed and returned the survey. Data have been entered and data analysis is ongoing. A conference for these RECs is planned in October, 2008 and we have obtained a seminar grant from the Wellcome Trust for this conference. 2) We have gained experience with the use of WebEx (www.webex.com), an online web conferencing center, and Blackboard, an online Learner Management System (LMS). Both of these tools are tools are housed on an established website with the domain name of www.enrec.com (Egyptian Network of Research Ethics Committees). To test and assess these internet tools, we used the Webex Online Conference Center in February 2008 to broadcast a live session of an educational workshop for the REC members at Theodor Bilhariz Bilharz Research Institute to individuals in different countries in the Eastern Mediterranean Region (Egypt, Jordan, and Pakistan). The online conference tool has also been used to broadcast continuing educational presentations to different members of RECs across Egypt. We have used the Blackboard LMS asLMS as an Electronic Resource Center consisting of teaching of teaching materials, such as. background resource documents, research ethics codes, landmark articles in research ethics, links to other websites and forms and templates for investigators and REC members to use in the review process. We have given several individuals in Egypt passwords to gain access to the Blackboard LMS and all have successfully entered the LMS. Future Activities: The Electronic Resource Center will be further enhanced in the following manner: REC members will be able to post resources of mutual interest [e.g., articles, Investigator Application form, REC checklist for initial and continuous review, elements of informed consent as well as an example of informed consent in Arabic, Financial conflict of interest disclosure statement, Statement of confidentiality, and Standard Operating Procedures (SOPs)]. The WebEx platform will enhance live electronic connectivity between members, making possible broadcast of REC meetings so that members can share their experiences. The Resource Center in conjunction with WebEx will also make possible online training by making research ethics literature, course content, and recorded presentations readily available and, by making available common application processes, will ensure greater consistency in the research review process; Conclusions: We have made initial steps in the formation of a network of RECs in Egypt. A baseline survey of RECs to determine needs and areas of weakness was distributed and a significant majority of the RECs completed the survey. We have also piloted tested two internet tools that will promote electronic connectivity among RECs and enhance distance learning opportunities. Our initial results demonstrate that these internet tools are useful and feasible in the Egyptian electronic environment.
Implementing a Protocol and Consent for Human Biospecimen Collection and Future Research Use
Memorial Sloan-Kettering Cancer Center
Roy Cambria; Collette Houston; Roger Wilson, MD; Robert Wittes, MD

Topic: Informed Consent

Problem/Issue Statement
In 2005, the Physician-in-Chief in collaboration with senior leadership at Memorial Sloan-Kettering Cancer Center (MSKCC) conducted an analysis of our institutional human biologic specimen collection and consenting process. This process had a series of limitations that were evaluated and a proposal for a centralized banking protocol which would comply with all human subjects’ protection, genetics, and privacy regulations in regards to biospecimen collection, was considered.

Description of Program/Research
The outcome of the analysis was an institutional-wide human biological specimen collection protocol to be used by investigators across all departments. The protocol outlines policies and procedures for collection of human biologic specimens at MSKCC while ensuring documentation of informed consent/research authorization for storage and future use. The protocol enrolls new patients having a test or procedure with potential to provide excess specimen that can be banked for future research or who has already had a procedure that has yielded left-over specimen presently in the archive. The new institutional wide biospecimen protocol was reviewed by legal council to ensure compliance with human subjects’ protection, genetics, and privacy regulations before being approved by the MSKCC IRB/PB in November 2006. The protocol was piloted in two surgical services and gradually expanded across the institution. Since 2007, we have taken several steps to continually improve the process including: 1) 1-page for signature, 2) an online web-based registration system, 3) simplified specimen-specific future use questions for patients, 4) eliminated need for eligibility checklists, 5) translation of consent into the top 6 non-English languages, and 7) updated the forms for retrospective and prospective use of collected samples. At the end of 2009, there were 12,700 participants registered to the protocol. The centralization of the process for human biological specimen collection allows all investigators at MSKCC to collect biospecimens to populate our bank for future research use, ensure patient confidentiality, and standardized consenting procedures which comply with federal regulations. In this poster presentation, we will outline the reasoning for change, the outcome, and the continuous revisions to improve the consenting process and protection of human subjects.
Improving Response Time for IRB Expedited Reviews
Mrs. Darlene S. Knox; Mrs. Julie R. Wakefield; Mrs. Lori L. Davis, MD

Topic: IRB Operations

Problem/Issue Statement

Objective: The IRB initiated a quality improvement project with the following goal: • Decrease the time from IRB expedited review to correspondence to investigator and research assistants

Description of Program/Research

Methods
An in-depth review of the IRB process for Expedited Reviews was conducted. Under the old process, which only involved the IRB Chair and Vice-Chair to conduct the reviews, it usually took 14 days or more to receive a response; and the correspondence was either hand-delivered to the investigator and research assistant via placing in their mailbox or awaited pick-up from the IRB office by the investigator or research assistant. A Delegation of Authority for the Expedited Review Process of Experienced IRB Members was implemented by Chief, Research and Development. Experienced IRB members are those IRB members who have at least 6 months of experience working on the IRB. Experienced IRB members are designed by the IRB Chairperson to conduct reviews using expedited procedures and are responsible for the thorough review and recommendation for approval, approval with stipulations/modifications, or referral to the full IRB board. The expedited reviewer must not have a conflict of interest in regard to the research project. In reviewing the research by the expedited procedure, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited review procedures, i.e. by convened IRB. The IRB Administrative Staff implemented an electronic response for delivery of correspondence to investigators and research assistants by emailing via Microsoft Outlook the IRB response as an attachment. The following was measured and compared: the time from IRB expedited review to correspondence to investigator and research assistants using the new Expedited Review Process. In addition, feedback was solicited from the investigators, research assistants, and experienced IRB Members regarding the changes implemented in the IRB Expedited Review Process.

Results
The average number of days from IRB expedited review to correspondence to investigator decreased from 14 days or more to 5 days or less. Increased satisfaction with the new IRB Expedited Review Process was reported by the Experience IRB Member, which helped to foster more involvement with human subject protections. The investigators and research assistants also reported an increase in satisfaction with new IRB Expedited Review Process.

Conclusions
The number of expedited reviews that travel through the IRB office can be overwhelming. That is why it is important for IRB offices to monitor and change processes as necessary for efficiency. Streamlining the IRB Expedited Review Process will definitely create a more efficient means of communication.
Incidental findings in neuroimaging research: striking the right balance

The Mind Research Network
Ms Jody M. Shoemaker; Dr. John P. Phillips; Ms Linda Petree; Dr. Vince D. Calhoun; Mr Raul de La Garza; Dr Sarah Feldstein-Ewing; Dr Reyaad Heyak; Dr Kent A. Kiehl; Dr Andrew Mayer; Dr Pilar Sanjuan; Mr Adam Scott; Dr Mark T. Holdsworth

Topic: Ethics and Risk Assessment

Problem/Issue Statement

Balancing researchers’ needs with subjects’ rights is an essential issue in medical research. This is perhaps most clearly exemplified by the conundrum of incidental findings (IFs) in neuroimaging research. Published literature consistently shows that 2-8% of children and adults have clinically significant findings noted on MRI scans, some of which are potentially life-saving if identified early and referred appropriately. But how should research MRI scans be evaluated? What is the ethical imperative? Should all readable scans be interpreted by a neuroradiologist? If so, do all subjects receive their MRI readings, or is the decision regarding subject notification up to the individual principal investigator (PI)? Who bears the cost of this obligation? Our institution has created a plan to respond to the myriad ethical, legal and practical implications when dealing with IFs in neuroimaging research. This poster summarizes the Mind Research Network’s (MRN) process of identifying and responding to IFs, striking what we feel is an appropriate balance between important ethical principles such as respect for persons, beneficence and paternalism, as well as responding to the needs of multiple researchers.

Description of Program/Research

Upon enrollment into an imaging study, subjects are made aware of MRN's commitment to having scans read by a neuroradiologist and the reporting procedures for scan results. The information is communicated verbally and in the written consenting process explaining the possibility of identifying an unexpected brain abnormality. Using customized and commercially-available free software, MRN has created a secure, centralized, radiological review process which sends an electronic report to the PI, while also providing every subject a copy of their MRI scan results. In addition to the mailed and hand-delivered letters, any findings that the neuroradiologist determines need an urgent or immediate referral (Leikert scale rating of 4 or 5 out of 5) are brought to the attention of the medical director, who contacts the subject directly, explains the results, and assists in arranging follow-up clinical care.

Program Evaluation

Working in collaboration with our Institutional Review Board (IRB), investigators, neuroinformatics and information technology teams, MRN has successfully developed an automated radiology review system that could be implemented at other organizations. Of the nearly 6000 scans reviewed at our institute, 43% have had an IF identified through the radiological review process. Of the 2566 reviews with IFs, 30% required no referral, 12% were a routine referral and 0.5% required urgent or immediate referral. Approximately 50 subjects have been personally contacted by the Medical Director regarding clinically significant abnormalities over the past year. In addition to the mailed notification of abnormalities, our system allows for subjects and physicians to request copies of scans and reports from prior study participation. This feature is beneficial when a brain abnormality is later discovered, such as recent inquiries involving multiple sclerosis and dementia diagnoses.

Suggestions for Implementation at Other Sites

Current recommendations in the literature suggest that all imaging research institutes need to create a plan to deal with IFs. Our current procedure fulfills ethical responsibilities consistent with the Belmont Report: subjects have a right to know their MRI scan results, regardless of what the findings are (respect for persons), which may now or in the future have benefit for the subject (beneficence), and they have the right to be treated similarly across different studies (justice). There has been a financial cost associated with MRN's decision to have a neuroradiologist read all MRI scans and notify subjects and PIs of the results, however by centralizing the process in our organization we have been able to minimize costs to the researchers and ensure that all ethical principles are being met while...
enhancing community goodwill. We suggest a similar model should be implemented at other institutions.
Increasing Institutional Oversight for Multicenter Protocols: Development of an Institutional Office

Memorial Sloan Kettering Cancer Center
Stephanie A. Karpoff; Ann Rodavitch; Roy Cambria; Collette Houston; Roger Wilson, MD

Topic: IRB Operations

Problem/Issue Statement

In recent years, the number of multicenter protocols coordinated by Memorial Sloan-Kettering Cancer Center (MSKCC) has increased exponentially. At the conclusion of 2009, there were 65 active MSKCC-coordinated multicenter protocols spanning 6 clinical departments and involving 137 unique sites in 33 U.S. states and 10 countries. Until recently, regulatory oversight was largely investigator dependent and staff efforts were duplicated around the Center. In December 2009, the MSKCC Office of Clinical Research (OCR) established the Multicenter Protocols Group (MCPG) to provide institutional support for MSKCC coordinated multicenter protocols. The goals of the MCPG are to institute standard policies and procedures, as well as provide tools and training to ensure participant safety, regulatory and protocol compliance, and data integrity for all MSKCC led multicenter protocols.

Description of Program/Research

A manager dedicated to this effort was hired and a steering committee of OCR members was established to review ongoing program development. Within its’ first 6 months, the MCPG met with key staff from each department and researched multicenter programs from other institutions. Several key resources were developed and implemented:

1) An institutional Standard Operating Procedure (SOP) to establish regulatory requirements for the MSKCC PI and participating sites, and sanctions for non compliance,
2) A training module based on the SOP,
3) Standard protocol language for therapeutic and non-therapeutic MSKCC-coordinated multicenter studies,
4) Pre-IRB MCPG review of new and amended MSKCC-coordinated multicenter protocols,
5) An intranet page posting best practices, definitions and templates useful in multicenter protocol management,
6) An audit of MSKCC IRB/PB files for participating site IRB approvals, and
7) An upgrade of MSKCC’s Protocol Information Management System (PIMS) enabling research staff to electronically track each site’s “protocol life cycle” and corresponding approval documents. Research staff can view site role, status, latest amendment approved and continuing review date. The system generates reports and sends automatic e-mail reminders to investigators for upcoming submission due dates.

Establishing an Institutional program for oversight of multicenter protocols improves regulatory compliance and provides resources for research staff that mitigate individual workloads. The MCPG will continue to develop additional materials for the “toolkit,” formalize MCPG review process so that MCPG approval is required at the time of site initiation, and work closely with the Clinical Research Informatics group to develop procedures and training for web- based data entry by participating sites.
Indigenous IRBs: Navajo Nation as a Case Study
Lane Fischer; Beverly Becenti-Pigman

**Topic:** Special Populations

**Problem/Issue Statement**

In 1995, the Navajo Nation Council created the Navajo Nation Human Research Review Board (NNHRRRB) to transfer human subjects research decision-making from the Indian Health Service to the sovereign Navajo Nation. In 2002, the Navajo Nation Human Research Code extended broad authority to the NNHRRRB to review, approve, and monitor all human research and to ensure that the research is beneficial to the tribe and consistent with Navajo Nation values. Each phase and additional criteria have solid reasoning behind them. Most researchers and university IRB members are unfamiliar with the Navajo phases, additional criteria, and reasons behind them. After first receiving university IRB approval (which is required by NNHRRRB), researchers are often confused and delayed in their Navajo approval process. Furthermore, the Navajo Nation has been a pioneer in indigenous IRB's and other tribes are following their lead to create their own boards, phases, and criteria. The intended outcome is to orient attendees to (a) indigenous IRB's, (b) the NNHRRRB as a case study of a sovereign nation IRBs, (c) illustrate the reasoning, phases, and additional criteria imposed by an indigenous IRB, and (d) encourage support and collaboration with indigenous IRBs.

**Description of Program/Research**

Rather than being a program per se, Brigham Young University has explicitly stated its support for the Navajo Nation's sovereignty and the NNHRRRB's authority, reasoning, phases and additional criteria. We have developed a working relationship with the NNHRRRB to educate ourselves, facilitate NNHRRRB approval of university sponsored research, and educate our students and researchers. The NNHRRRB has sent representatives to our campus and we have attended conferences and training on the Navajo Nation. Our on-going mutual support is enhancing understanding.

**Additional Information**

This information would best be presented in a working session at the conference. Mrs Becenti-Pigman, founding member and Chair of the NNHRRRB, is a compelling speaker who can provide the history and reasoning behind each phase and additional criteria imposed by the NNHRRRB. Lane Fischer's role would be to facilitate discussion in the session, and to illustrate BYU's efforts to support the NNHRRB, coordinate our efforts, & educate our university researchers regarding the ethics of research conducted on the Navajo Nation. Ashley Schofield has forwarded an earlier proposal to Mariellen Diemand to be considered as a conference session but recommended that I also submit this as a poster.
Internet Resources for Subject Recruitment: The Implications
Anne E. Gupman, MA, CIP; Cecile Shindell; Pamela Kearney, MD; Susanna S. Sung, MSW; Barbara I. Karp, MD

Topic: Subject Recruitment or Internet Resources in Research

Problem/Issue Statement
Recruitment for human research participants requires that study information be presented in a manner and in venues that are non-coercive, that do not over-emphasize potential or secondary benefits and in a way that reaches appropriate populations without stigmatizing or singling out individuals. Traditional recruitment methods have relied most heavily on publication or posting of written notices. Traditional recruitment typically presents limited information about the study and is generally one-way, with information passing from the researchers to the public. Interested potential participants are then required to contact the research team for additional information or for enrollment. Use of the World Wide Web presents unique challenges for subject recruitment.

Description of Program/Research
The benefits of using new and social media have been widely proclaimed, especially by companies touting recruitment services. However, the potential problems, pitfalls, and ethical issues raised by internet recruitment have rarely been addressed. In this poster, we will explore the implications, both positive and negative, of using internet resources, particularly social media (such as Facebook, Twitter, blogs, and MySpace) as well as search and advertising services (such as Google), chat rooms, on-line support groups, and commercial websites for research subject recruitment. Understanding new media use and misuse for subject recruitment is crucial for IRBs and investigators.
Interpretation and application of 45 CFR 46 in the context of vector biology research
Laura L.S. Youngblood, MPH, CIP; Wendy L.V. Carr, PhD

Topic: Regulations and Guidelines

Problem/Issue Statement
Vector biology research is unique from a human subjects perspective; the vector is the primary subject of study, and the role of human participants is often peripheral. Humans are often not "subjects" as defined in 45 CFR 46.102(f); when they are subjects, it is often not by design. Regardless of whether they are subjects, human participants are exposed to research risks. This makes vector biology research challenging to consider in the context of human subjects regulations and oversight. Examples of such research include studies that involve in-home collection of mosquitoes or use humans as live attractants. Anecdotal reports and informal discussions with research professionals suggest incomplete understanding on the part of IRB members as to the nature of this type of research and the methods employed, and that IRBs do not always exercise the inherent flexibilities present in the Common Rule. In this presentation, we discuss four areas of the Common Rule that afford flexibility to IRBs and provide additional suggestions for IRBs to consider when evaluating vector research.

Description of Program/Research
We focus on the following four topics: definition of a human subject, assessment of risk, approvability criteria and informed consent. For each area, information will be presented regarding pivotal considerations that are encountered in vector biology research scenarios. Definition of human subject: Although this type of research by definition involves intervention or interaction with individuals, it often does not involve obtaining information about those individuals. Therefore mechanisms outside the strict application of the Common Rule can be considered. Assessment of risk: The definition of minimal risk as relative to the probability and magnitude of ordinary harms and discomforts affords IRBs latitude in assessing risk level. Approvability criteria: Regulatory flexibility exists both in the determination of whether particular requirements are applicable and in the degree to which the requirements are applied. Informed consent: While acknowledging that informed consent is an important component in respecting participants' autonomy, regardless of whether they are subjects, the applicability of individual elements, as well as waivers should be considered. Additional suggestions: Incomplete understanding of the methodologies employed and the inherent risks is a common barrier to IRB review of vector biology research. It is helpful for IRBs to consult with an independent entomologist to assist in understanding these aspects of the research. Conclusions: It is important to protect the rights and welfare of participants in research, regardless of whether they are subjects. However, application of requirements that are not strictly required by regulation may not provide meaningful protection, and may result in substantial delays or even disapproval of important research that is not inherently unethical. IRBs should be encouraged to utilize flexibilities inherent in the regulations when assessing vector biology research that involves human participants.

Additional Information
Disclaimer: The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
IRB Management of External Adverse Events (AEs) and Unanticipated Problems (UPs)
Cedars-Sinai Medical Center
Ms. Ambereen A. Burhanuddin; Ms. Leah Silbert; Ms. Keren Dunn; Ms. Eifaang Li

**Topic:** Post Approval Monitoring

**Problem/Issue Statement**

The volume of individual external adverse event reports from multi-center sites submitted to IRBs - often lacking in context and detail - has been noted by many as hindering, rather than enhancing, the ability of IRBs to protect human subjects. According to OHRP guidance on AE reporting requirements, “it is neither useful nor necessary… for reports of individual adverse events occurring in subjects enrolled in multicenter studies to be distributed routinely to investigators or IRBs at all institutions conducting the research”. Further, under FDA guidelines, “An individual AE occurrence ordinarily does not meet these [reporting] criteria because, as an isolated event, its implications for the study cannot be understood”. Additionally, the OHRP and FDA clarify that only a small subset of adverse events occurring in human subjects participating in research are unanticipated problems that must be reported under 45 CFR part 46 and 21 CFR parts 56, 312, and 812. In accordance with OHRP and FDA guidance, and in an effort to streamline post-approval monitoring while maximizing the utilization of resources, the Office of Research Compliance and Quality Improvement (ORCQI) at Cedars-Sinai Medical Center (CSMC) attempted to address this issue facing IRBs across the country and around the world.

**Description of Program/Research**

After a thorough review and understanding of the regulations that govern the reporting of External Adverse Events, the CSMC IRB External AE reporting policy was revised to require the submission of only those external adverse events reports that might constitute Unanticipated Problems involving risks to subjects or others (UPs). Consequently, the External AE reporting form and process in the electronic IRB system was also revised to be congruent with the revised reporting policy. This enhancement to the electronic AE reporting form incorporates the fundamental elements of determining whether an adverse event might constitute a UP. Based upon the investigator’s responses to these fundamental questions, only those reports determined to be possible UPs are reviewed by ORCQI staff, and then by an IRB Member. External AEs that are deemed to be not reportable by the system do not go through the IRB review process. For these non-reportable events, an automated letter is generated stating that these events did not meet the CSMC IRB’s External AE reporting criteria. This automatically generated letter was incorporated as a critical component to assist the research community with recordkeeping and meeting requirements of their sponsors and monitors.

**Program Evaluation and Findings**

Since the implementation of the revised External AE policy and application form in July ‘09, the ORCQI has seen a dramatic decrease in the number of such reports that require IRB Staff and/or Member review. The feedback received from system users has demonstrated that this revision has been a welcome change. Further, this marked reduction in External AE reports requiring review – that typically have no impact on the study – have enabled the IRB to focus on those reports that may have a possible impact on the study, namely, possible Unanticipated Problems.

**Suggestions for future program usage at home**

Based on the extremely positive results post-implementation, the ORCQI is planning a quality assurance initiative that will include a survey of system users as well as an audit of external AE submissions automatically deemed not reportable under the revised application. If any potential weaknesses are identified, these will be addressed in subsequent revisions. Assuming this effort confirms that the system is working as intended, the ORCQI may consider implementing similar functionality to the Internal AE application.
Suggestions for implementation at other sites

The ORCQI encourages other sites to modify their own policies and procedures for submission of external AEs to focus on capturing only those events that represent possible UPs. Processing these reports has long pulled from human resources which could readily be utilized on more meaningful research compliance and IRB review activities. One concern has always been that industry would be apprehensive of any attempt to limit the reporting of external AEs; however, that fear has not been borne out in our experience, likely due to clear policies and the automatically generated letter for the research team’s regulatory files. Further, the regulatory framework and guidance documents from both OHRP and the FDA clearly support this change in practice. As with any significant change to policies, procedures, or systems, it is essential to get input from all stakeholders, including IRB staff, IRB members, investigators, research coordinators, and institutional leadership, prior to implementation.
IRB Member Education: Assessing the Effectiveness of Member Education Programs and Using Member Feedback to Implement New Training Initiatives

*University of Pennsylvania*

Megan K. Singleton; Barbara Santiago; Jennifer Holmes; Yvonne Higgins; Emma Meagher; Adina Lieberman

**Topic:** IRB Operations

**Problem/Issue Statement**

Appropriate training of new IRB members and continuing training for ongoing members is a challenge facing each IRB. Often member training programs focus only on standardized training materials and rarely address the unique issues that may face individual IRBs based on the type of research conducted at that institution. Similarly, most standardized IRB member training programs fail to identify and address the specific training needs of individual IRB members.

**Description of Program/Research**

The University of Pennsylvania IRB provides both new member training and ongoing member training. Ongoing member training includes topic-specific training initiatives at the IRB meeting and specialized training programs including member training for non-scientists and training for Committees that review research involving prisoners. In order to assess the effectiveness of member training initiatives in addressing the complex training needs of IRB members, the University of Pennsylvania IRB has incorporated a member survey into the annual member self-evaluation. The purpose of this survey is to evaluate current training initiatives, obtain important information about the IRB member experience and use member feedback to adopt and implement new training initiatives.

**Additional Information**

Details of How the Program Was Evaluated: IRB member self-evaluations were completed in May 2010. In July 2010 members will be provided with a web-link and log in code for completion of an anonymous web-based survey. Data obtained from the survey will be used to develop new member training initiatives and used to educate the IRB staff regarding member needs. Suggestions for Future Program Usage at your home institution: The IRB will implement programmatic changes in response to IRB member feedback. These changes will be assessed within 6 months after implementation and again at the annual member evaluation in May 2011. Suggestions for Implementation at other sites: Incorporating a member assessment of IRB training initiatives and IRB effectiveness in responding to member needs is a strategy that can easily be adopted by any institution. The Penn questionnaire can be used as a model for development of an institution-specific assessment tool.
IRB/QI Educational Focus Group Program
*Winthrop University Hospital*
Tina P. Berry, CIP; Diane Redmond, CCRA; AnnMarie Martin, CCRC; Sue Boglia-Nitsch, RPh, MHA

**Topic:** IRB Operations

**Problem/Issue Statement**

Auditing is an integral part of continuous improvement within Winthrop-University Hospital. The institutional review board performs audits for compliance in order to evaluate safety of participants as well as making sure the Principal Investigator (PI) is complying with Good Clinical Practice (GCP). In 2004, the IRB implemented a Not-For Cause Audit Program. The mission of this program was to identify, evaluate and correct non-compliance issues before they escalated to a "For Cause Audit." The IRB/QA Focus Group Program will establish and maintain a continuous educational forum for improving the quality of research practices within the Institution after a For Cause Audit. The primary goal of the Program is to improve the quality, performance and efficiency of clinical research without appearing punitive after an IRB Audit. The Program seeks to foster collegial relationships and create an environment that will enhance networking relationships among researchers and the Institutional Review Board. Our secondary goal is to enable Investigators and their research team to understand the ramifications of not following regulatory guidelines and make thoughtful decisions about research participation, while providing a reference resource for use in advancing protections

**Description of Program/Research**

The Institutional Review Board Administrative Office in conjunction with the Quality Assurance Manager have developed an Educational Program which focuses on the Principal Investigators as well as the entire research team. The IRB consistently conducts at least two audits monthly and within that month occasionally there may be cause to conduct a For-Cause -Audit. During these audits when issues arise that are considered non-compliant. Any Investigator who has been found to be non-compliant is required to attend along with his/her research team an IRB/QI Focus Educational Seminar. The program is 2.5 hours long and consists of 43 slides that cover Good Clinical Practice (GCP), OHRP/FDA investigations, Reporting of UAPs, Informed Consent/Assent, Non-English Speaking Subjects and documentation. Templates and additional guidance educational materials are provided to assist with their education. Each talk is customized to focus on the specific non-compliance issues shared by the majority of the attendees. All talks will also include the basics mentioned above

**Additional Information**

**Evaluation Method:** The Program will be evaluated for effectiveness on an annual basis. Evidence of improved research processes is based on re-auditing the same investigators from the previous year.

**Results:** To date, results are pending will be available in May 2011 Conclusions are pending.
IRB Satisfaction - A Quality Improvement Initiative

*Columbia University Medical Center*

Lauren T. Privitera; Elaine Larson; Scott Beardsley; Susie Kim; George Gasparis; Brenda Ruotolo

**Topic:** QA/QI

**Problem/Issue Statement**

Columbia University Medical Center (CU) has five Institutional Review Boards (IRBs) including one behavioral and one IRB dedicated to the review of oncology studies. CU utilizes a web-based IRB submission system named RASCAL. All protocol events are submitted through the RASCAL system. Cumulatively, the IRBs review approximately 5500 events per year. The mission of the CU IRB is to enhance and facilitate the ethical conduct of human subjects research; Their vision is to establish and maintain excellence in its human subjects protection program and to provide the best service possible to the CU research community. One of the efforts put forth to accomplish the CU mission and vision is a quality improvement project. The objective of this quality improvement project is to identify strengths and areas for improvement in the IRB process. The project utilizes focus groups and satisfaction surveys to identify researchers perceptions of the following core areas of IRB competency: a) user friendliness of the IRB submission system b) ease in identifying the IRB/IRB staff responsible for facilitating the review of an event c) responsiveness of IRB staff d) quality of review e) timeliness of review f) effectiveness of communication g) effectiveness of educational sessions

**Description of Program/Research**

The quality improvement project was implemented in January 2010 and consists of 2 distinct methodologies; Focus groups and satisfaction surveys. In order to ensure the program focused on matters relevant to the research community, focus group discussions were conducted. The 14 focus group participants varied in levels of experience and included individuals who submitted to the biomedical as well as the behavioral IRB. The goals of the focus group were to identify areas of IRB weaknesses and strengths and to pilot test the IRB satisfaction survey. Each month, using SurveyMonkey, an email with a link to the IRB satisfaction survey is sent to key personnel of randomly selected event (new protocol, renewal and modification) approvals for each of the five IRBs. Data on the IRB protocol number, type of event, level of review, IRB review committee, level of experience and role of respondent is recorded on each survey response. The quality improvement project is an ongoing initiative aimed at improving quality. Data will be collected continuously and reviewed by senior management for process refinement, implementation and reanalysis.
Is Input from Research Colleagues Helpful? – An IRB Administrator’s Solution to Minimizing the IRB Burden on Behavioral Science Investigators
Sharon Zack, MS; Kerry Levin, PhD

**Topic:** IRB Operations

**Problem/Issue Statement**

Engaging in the IRB review process can be a frustrating and lengthy experience for investigators. Often behavioral science researchers are unsure as to what is required in a submission, what specific details the IRB is looking for, or what dates the IRB meets. The IRB process can feel like an intentional blockade denying investigators access to conducting their research. Definition of Intended Outcome- The research community will feel more connected to the process, have a voice in the decisions, be in close touch with any changes as they occur, and ultimately more satisfied with the results of their review.

**Description of Program/Research**

Study Area IRB Representatives (IRB REPS) are individuals throughout the organization that come together and support the needs of their investigators. These individuals are researchers who have scientific background in the study areas they represent. They were also chosen in this role because of their familiarity with business operations, the IRB process, and are well respected within the organization. An IRB REP’s role includes the following responsibilities: • Attend a monthly IRB REP meeting to discuss the latest protocols under review and other emerging IRB issues • Review IRB applications before they are submitted to the IRB office • Accompany investigators to full Board reviews • Support investigators throughout the review process • Contribute to important changes to the review process (new electronic submissions) • Stay connected to the larger research community through academic articles, conference presentations and other pertinent human subjects protections news.

**Additional Information**

Evaluation is ongoing. Based upon qualitative feedback, the addition of this program has been positively received. Plans for the future include developing and implementing a customer satisfaction survey to collect quantitative feedback about the IRB process, role of the reps, and suggestions for improvement.
Knowing is Half the Battle—What the Numbers are Telling us About the “Health” of Peoria’s Community

IRB
Mindy Reeter, BS, CIP; Andrew Olmsted, MBA

Topic: QA/QI

Problem/Issue Statement

The complexity of IRB benchmarking is poignantly illustrated in the immortal words of Dan Nelson, SACHRP’s Subpart A Subcommittee Co-Chair, when he says “When you’ve seen one IRB…you’ve seen one IRB.” Due to differing definitional interpretations across institutions, comparing IRBs is like comparing apples to oranges. As a result, literature regarding IRB benchmarks is extremely limited and offers little guidance for setting goals for timely turnaround of materials or metrics for quality improvement. In response, the UICOMP IRB, in conjunction with IRBNet, has developed a reporting mechanism for cycle time and portfolio analysis to manage IRB efficiencies. Since the implementation of IRBNet in April 2008, UICOMP has reliable data for all IRB activity.

Description of Program/Research

Serving as its own control, IRB data were analyzed for characteristics including research portfolio characteristics, expedited and convened review cycle times (time to decision and letter), item type (amendment, continuing review, UPIRSO, other, new studies, closure/final reports), workflow values and research community composition (novice vs. power users).

Results

2009 (12 months) IRBNet Data
- IRB membership should reflect the expertise and diversity appropriate for addressing the varied characteristics of the research portfolio. • Be conscious of social/behavioral components of biomedical studies such as QOL questionnaires when calculating % of social/behavioral research activity. • Early identification and planning for UICOMP calendar events and PRIM&R travel may minimize the impact of these situations on time to decision/letter. • Early identification of meeting dates (5 week months vs. 4 week months) and submission deadlines (variable during holiday months) may minimize the impact of these situations on time to decision/letter. • Identify workload as precisely as possible in order to accurately gauge time commitment required for meaningful review: Identified need to increase choices for item type in IRBNet to delineate “other.” • Be conscious of temporary “ballooning” of item types for review when gauging workload calculations for departmental budgeting (ex: one time Oncology staffing change activities; anticipated to sharply reduce.) • Continuous human subjects training is warranted: Adverse Event submissions drop due to submission refinements and education of investigators. • High percentage of novice investigators identifies priority for education of investigators. • Further delineation of the composition of novices (residents, medical and nursing students) can allow tailoring of investigator education for maximum group benefit. Research portfolio characteristics (n=558): Biomedical: 96%; social/behavioral: 4%; minimal risk: 15%; greater than minimal risk: 85%; Active (retrospective chart reviews): 12%; active—open to enrollment: 48%; active—closed to enrollment: 35%; active—long term follow-up study: 3%; active—data analysis only: 2%. Time to decision/letter: Expedited reviews (81% of review type)—14 days to decision; Convened reviews (17 % of review type)—25 days to decision/3 days to letter. IRB Exemptions (2% of reviews). Item types (volume/percentage: Amendment/revision: 407/15%; continuing review: 520/20%; adverse events/UPIRSOS: 553/21%; other: 729/28%; new studies: 198/8%; closure/final reports: 159/6%. Research community constitution (registered users n=344 reported as volume/percentage): Novices (1 study): 156/45%; power users (> 1 study): 188/55%. Workflow (volume/workload per 2.8 FTE): Active studies: 558/199/FTE; submissions: 2637/942/FTE; letters generated: 2727/978/FTE. Future Program usage: The UICOMP IRB will continue to use these benchmarks for the management of IRB membership, PI and IRB member education, staffing decisions, time management, customer service and departmental budgeting. UICOMP intends to share this data with other IRBNet users in an effort to glean “best practices” from similarly organized HRPP programs. Suggestions for other sites: Implementation of a database system that can track reliable and consistent data empowers an institution striving for continuous quality improvement. Quantitative and qualitative analyses of IRB data is powerful...
evidence when making management decisions and/or arguments at a departmental and institutional level.
Knowledge, attitudes and practice of health care and research ethics: questionnaire survey among postgraduate medical, dental and nursing students
Dr. Kaleeluvilayil Raghavan Nair Chandramohanan; Dr. Nandini K. Kumar; Dr. Sreekumar, R; Remadevi, J

Topic: Healthcare and research ethics

Problem/Issue Statement

The present study is to assess the knowledge, attitudes and practice of health care and research ethics among postgraduate (PG) medical, dental and nursing students of Government Medical College, Trivandrum, India in order to plan strategies to improve the knowledge about application of ethical principles in practice and research.

Methods: A self-administered structured questionnaire about knowledge, attitudes and practice of healthcare and research ethics was devised and tested. It was distributed to all the 2nd year and 3rd year medical and dental post graduate students (PGs) and 2nd year nursing PGs.

Results

With regard to knowledge about ethics 156 responses were analyzed i.e., 104 from medical, 31 from dental and 21 from nursing PGs. 14% of the medical and 23% of dental PGs did not know the contents of Hippocratic Oath whilst 5% of nursing PGs did not know the Nurses Code. Nuremberg Code and Helsinki Declaration are known only to a few PGs. Most of the PGs responded that knowledge of ethics is very important in her/his work. A statistically significant differences in the attitude was observed for three factors- respecting patients' wishes, charging more fees from financially sound patients for treating the poor, and need to adhere to ethical conduct to avoid legal problems (P<0.05). There was wide temporal variation in the frequency with which the respondents encountered ethical issues. 39% of medical and 19% each of dental and nursing PGs stated that they never encountered ethical issues. More than 90% of the PGs responded that ethics committee is present in her/his institute. In practice 90% of nursing PGs, more than 60% of medical and a 25% of dental PGs responded that they respected patients’ decision, when people belonging to certain religious beliefs refuse to take treatments. On encountering any ethical problem, majority of the medical and dental PGs preferred to approach the head of the department and, nursing PGs their immediate supervisor. Strategies would be planned based on the present study to bring change for the better in the ethical behavior of healthcare professionals and researchers.
"Mission Creep" and the Expanding Responsibilities of IRB Staff
Jennifer Morris; Rachel Topper-Greco; Michael Chapple; Marjorie Gillespie; Alex Noury; Laura Kimberly; Nanette Suksta; Donna Howard; Catherine Little; Pamela Kearney, MD; Barbara Karp, MD

Topic: QA/QI

Problem/Issue Statement
To better characterize and understand the responsibilities of IRB Staff.

Description of Program/Research
IRB "mission creep" has been described in recent articles as requiring IRBs to take on responsibilities additional to and often beyond their primary mission of reviewing and approving research proposals and protecting research participants. Less attention has been paid to the parallel "responsibility creep" this expansion of scope, as well as the increasing regulatory environment, places on IRB staff.

Methods
We are querying IRB professionals and staff within the NIH Intramural Research Program with regard to the range and nature of their responsibilities and time needed to complete various tasks. Additional data will include staff demographics (e.g. age, sex, education, professional certification, experience, and time in the position).

Results
The NIH Intramural Research Program encompasses 12 IRBs and employs approximately 25 FTEs as IRB staff. The data collected will be used to better understand the nature and challenges of IRB staff positions.

Next Steps
We will use the results of this study to develop clearer expectations and job descriptions for IRB staff. The data will also allow us to identify, and hopefully mitigate, "responsibility creep" for staff and allow them to focus more intently on their primary mission—assisting IRB’s and institutions in protecting human research subjects.

Additional Information
This research was supported by the Intramural Research Program of the NIH.
Ongoing Consent Monitoring: A Critical component of Human Subject Protections

National Institute of Mental Health & Combined Neuroscience IRB
Katherine Whorton; Carol Squires; Mary Ellen Cadman; Julie Brintnall-Karabelas; Maryland Pao; Barbara Karp, MD

Topic: Special Populations

Problem/Issue Statement

OHRP and Federal regulations make it clear that informed consent does not end once the written informed consent form is signed. Consent is an ongoing process and must remain intact throughout the course of a subject’s participation. The National Institute of Mental Health (NIMH) Office of the Clinical Director established the Human Subjects Protection Unit (HSPU), an independent, multidisciplinary team to provide potentially vulnerable subjects with multiple levels of protection during participation in clinical trials including ongoing consent for greater than minimal risk, inpatient protocols.

Description of Program/Research

The literature on informed consent tends to focus on the initial informed consent process. Frequently ongoing consent is inferred from a subject’s continued cooperation and the absence of verbal objection/withdrawal from the study. Such inferences may not be reliable or acceptable in subjects with psychiatric illnesses. We will identify issues and examples that occur during research participation which may affect a subject’s consent: - fluctuation in consent capacity to provide informed consent, - fluctuation in psychiatric symptoms - changes in personal, social, or home environment, family issues HSPU ongoing consent monitoring includes: - Assigning an HSPU Clinical Research Advocate (CRA) to each subject to monitor ongoing consent - Formulation of a subject- and study-specific monitoring plan including routine re-evaluation of capacity - Participation in interdisciplinary team meetings and direct communication with investigators - Written documentation - Ensuring monitoring plans and the results of monitoring are reported to the IRB We will present investigator experience and feedback regarding the HSPU monitoring of their protocols and subjects. Program Evaluation Program review and evaluation are conducted annually: - Number of protocols and subjects monitored - Results - 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. Our best practices can be adapted to other research venues.
Photonarratives: The Challenges of Securing the Privacy and Confidentiality of Participants in High Risk Contexts
Population Services International (PSI)
Meghan Bohren; Reid Smith

**Topic:** Ethics and Risk Assessment

**Problem/Issue Statement**

Researchers at PSI have conducted studies using photonarratives with two groups of participants in high risk contexts: clients of commercial sex workers (CSWs) in Haiti and injecting drug users (IDUs) in Thailand. Each participant received a camera and was instructed to photograph places, objects, and people s/he associated with previous experiences of engagement with CSWs or injecting drugs. The original Research Ethics Board (REB) submissions described the studies as “minimal risk” to participants, did not sufficiently justify the use of photonarratives over oral or written narratives, failed to describe the guidance that would be given to participants on what subject matter was acceptable to photograph, and offered a personal copy of potentially incriminating or lewd photographs to the participants. Both studies were consequently tabled at the full board meetings.

**Description of Program/Research**

Photonarratives are utilized as a qualitative research tool to provide the rich data that emerges when study participants are given an opportunity to document their lives and tell their personal stories. Photonarratives allow researchers to bring the target audience to life and help create a picture of the “typical” experience. Visual data, when combined with descriptions and explanations, provides marketers with access to the lived experiences of target audience members. Storytelling is a fundamental human way of relaying information, so data collection can feel more “natural” to both moderators and participants. Given the engagement in high risk behaviors studied in this research, it was imperative to construct additional safeguards to protect the primary and secondary participants.

**Additional Information**

Results The REB provided detailed feedback to the researchers, who subsequently designed a guidance document on photonarratives for these studies. The guidance document includes instructions for the participants, suggested subject matter for the photographs, information regarding the follow-up interview, and guidelines for participants to ask consent for secondary subjects who are photographed. The creation of the guidance document also resulted in setting a precedent for other studies involving photonarratives and the ability for researchers to conduct creative, audience-driven research involving visual images, but within a framework of higher consciousness of risks involved and closer adherence to accepted standards of human subjects protections.
Plain language training for researchers
Jessica R. Ridpath; Sarah M. Greene; Cheryl J. Wiese

**Topic:** Informed Consent

**Problem/Issue Statement**

Most institutional review boards (IRBs) recommend a reading level of 6th-8th grade for informed consent documents—a standard consistent with literacy assessments showing an average 8th-grade reading ability among American adults. But a 2003 study found that college-level research consents were common at US medical schools—and that only 8% of forms met institutional readability standards. Researchers are ethically obliged to ensure that consent forms are understandable to the subject. But writing in plain language is often an underdeveloped skill, and researchers face many readability challenges unique to our setting. When researchers "default" to scientific writing, comprehensibility of study materials suffers.

**Description of Program/Research**

Group Health Research Institute (GHRI) created the Program for Readability In Science & Medicine (PRISM) in 2005 to address this specific problem. PRISM evolved from an internal training initiative into a suite of readability resources for the national research community. Our new public-domain online training course will be freely available by June 30, 2010. We based the hour-long course on the PRISM Readability Toolkit and over a dozen in-person PRISM training workshops with researchers and IRB professionals. The overall goal is to make PRISM training more widely accessible. Course content includes: 1) Background on health literacy and readability; 2) Readability challenges in research and links to helpful readability tools; 3) Plain language strategies and pre-post examples from participant materials; 4) Interactive editing examples and exercises. A built-in evaluation will inform periodic assessments of the training’s usefulness. Seven beta-testers found the course helpful and suggested enhancements to boost its overall usefulness. This positive encouragement is congruent with evaluations of the PRISM Toolkit (more than 10,000 downloads from http://www.grouphealthresearch.org/capabilities/readability/readability_home.html since 2008). Our in-person workshops consistently receive high ratings, including a didactic session at PRIM&R’s 2007 Human Research Protections Program Conference in which more than 70% of attendees rated it as “excellent” or “very good.” A recent PRISM workshop at a regional OHRP community forum received the 3rd-highest rating among 19 breakout sessions (an average participant score of 4.6 out of 5). Few readability resources address specific challenges posed in research—which may explain why easy-to-read consent forms remain the exception rather than the rule. PRISM training was created to help research institutions change this trend. Proactive dissemination is central to widespread implementation. PRIM&R’s Advancing Ethical Research Conference is a prime venue for making the research community aware of this resource and engaging IRB professionals in dialogue about how to maximize its reach and usefulness.
Professors as Content Experts: The First Line of IRB Review
Nova Southeastern University
Dr. Jaime Arango; Dr. Ana Fins; Teri Hamill

**Topic:** IRB Operations

**Problem/Issue Statement**

How to enhance the interface between the IRB and the researchers within academic units at a large private university.

**Description of Program/Research**

The IRB system at Nova Southeastern University (NSU) employs a decentralized model whereby professors serve as "center representatives" to their academic units and link the IRB to researchers within those units. They also serve as IRB members, thus allowing for a two-way dialog between the IRB and its constituents. The system is evaluated via satisfaction surveys provided to end-users. These surveys also inquire as to turnaround time experience and opinion as to recommendations made by the center representative. In addition, the IRB solicits input from its members via survey procedures where members are asked to provide information about their workloads and internal operations. With respect to the home institution, we plan to continue to use the system but propose to enhance it with ongoing training of center representatives. Other sites could implement similar models by evaluating their own infrastructures and needs. In the poster session, we plan to discuss the benefits and challenges that a decentralized system presents.
Promotion of the research capacity building within a social insurance model
Daniel Bustos-Montero, MD; Maureen Carvajal, MSc; Carlos Fuentes-Bolanos, MSc; Melvin Navarro-Diaz, MD.

**Topic:** International

**Problem/Issue Statement**

One of the problems that has been found by the Institutional Net of Bioethics Committees, that include 44 Local Committees of Bioethics plus the Institutional Committee of Research Ethics from the Costa Rican Social Insurance (CCSS), has been the small amount of research that is been performed within the healthcare centers, including biomedical research. This is evident if it is considered that the CCSS has more than 46,000 staff members distributed in 2,695 centers along the country, with an actual universal coverage of Costa Rican population of around 87%. Data from the Division of Research Ethics (DRE) shows that only 192 research protocols were performed during 2008, from which 92% (176/192) corresponds to academic studies, in other words, research required to obtain a graduate or postgraduate degree. This issue reflects the lack of research culture within the CCSS, that added to the cadency of economic resources and research-trained staff, plus the work overload of personnel, produce that biomedical research, as any other research activities, does not contribute with the improvement in the CCSS healthcare services. The intended outcome is to promote biomedical and social insurance research, of quality and according to the ethical principles internationally recognized, through the implementation of a program that could warranty the respect to the existent regulation and, at the same time, supplies the necessary resources thus the researchers could perform their studies, and to incentive investigation in the CCSS, in a way that the results obtained from this activities could be used as an instrument to make that the healthcare units base their services in medical evidence derived from autochthonous studies.

**Description of Program/Research**

The structure implemented by the DRE in 2005, constituted the point of departure to promote biomedical research within the CCSS. This new structure established the regulatory framework that should be followed to warranty ethically human research. Once implemented this platform, the Division of Technical Support to Research (DTSR) was created within the Center for the Strategic Development and Information in Health and Social Security (CENDEISSS), with the aim to support the investigation and technological innovation processes. During 2008, the Fund of Investigation and Technological Innovation (FIIT) was established, as the first effort to finance and to promote those research projects, considered of institutional interest. This FIIT began with an initial budget of US$ 250,000 and it will be increasing, gradually, until the annual 1% of the total budget of CCSS could be reached. Indeed, the FIIT pretends not only the financial support of the research, but to endow what is being named “Research Time” to staff. This means that a percentage of the regular working hours should be assigned to perform activities related to the research, without affecting the normal healthcare services. As a mechanism to foment the quality of biomedical research, only the studies that have been previously approved by one of the committees from the Institutional Net of Bioethics Committees, assuring the accomplishment of the requirements of the Biomedical Research Regulation within the CCSS, could apply for the FIIT. To determine the research projects that will be financed, it should be considered the relation of the study to the strategic lineaments of the CCSS, the social interest as well as the economic and environmental impact of the study. Also, in order to have an optimal control of the economic resources, and at the same time, to prevent the potential conflicts of interest, the funds will be transferred, by budget modifications, to the unit where the study will be conducted, so the purchase of equipment and supply could be done as the institutional regulation establishes. This FIIT does not include payment to the investigator to perform the research. As well, this initiative proposes that the resources used during the research could be utilized, afterwards, by other professionals in the healthcare services provide by the CCSS.

**Details on how the program was evaluated**

Although this program is of recent creation, it is not possible to evaluate it appropriately; however, it needs to be mentioned that the different agents interested in this field have supported the initiative and are in the process of preparing the biomedical research in order to be submitted in a short-time period.
Suggestions for future program usage

There are several recommendations that could be made to improve this project within the CCSS, in different fields of action as biomedical research and social insurance research. Some of these recommendations are: a) to promote a research culture from the undergraduate level, to aim that the students include this knowledge as part of their routine activities as future healthcare professionals; b) to develop a multidisciplinary action strategy, including internal and external agents to the institution, thereby achieving the realization of collaborative research between public and private organizations in the country; c) to encourage biomedical research with a preventative approach, which seeks to address the leading causes of morbidity in the country, as well as other priority issues identified in the National Health Agenda of Costa Rica, thus achieving the realization of research with very high quality parameters and in accordance with the ethical principles that all research involving human subjects must comply, and d) to form a core of full-time researchers from different disciplines related to social security.
Protecting Human Subjects Participating in Mental Health Research via Initial & Ongoing Assent Monitoring
National Institute of Mental Health & Combined Neuroscience IRB
Carol Squires; Katherine Whorton; Mary Ellen Cadman; Julie Brintnall-Karabelas; Maryland Pao; Barbara Karp MD,

**Topic**: Special Populations

**Problem/Issue Statement**
Assuring the integrity of the informed consent process, while respecting the autonomy of potentially vulnerable subjects, is critical to ethical research. While less discussed, monitoring of the assent process either for minors or adults without consent signing capacity is equally important. Assent monitoring by the independent NIMH Human Subjects Protection Unit (HSPU) assures the autonomy of minors/adults without consent capacity is respected, that participation is free of coercion and assent remains intact throughout study participation.

**Description of Program/Research**
Assent is the affirmative agreement of an individual without consent capacity to participate in research. Federal regulations require active assent; failure of the subject to object to participation should not be construed as “assent.” We will review and discuss Federal regulations, relevant assent literature, how to obtain assent and recognize dissent. We will present the NIMH HSPU approach to protecting the rights of minors and incapacitated adults through assent monitoring. We will describe the disorders and studies which HSPU monitors. Sample aspects of an HSPU assent monitoring plan: - The assignment of an HSPU Clinical Research Advocate (CRA) to subjects - Initial Consent & Assent Monitoring - Formulation of an ongoing and study-specific assent monitoring plan - Participation in interdisciplinary team meetings and direct communication with investigators - 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 of protocols and subjects monitored - Results - 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. Our best practices can be adapted to other research venues
Rapid cycle quality improvement initiative to decrease initial protocol review time
Jennifer Marchitto, Monika Lau, Sandra Alfano, Pharm.D, Kathleen Uscinski, MBA

Topic: IRB Operations

Problem/Issue Statement
It is well recognized that the process of IRB review may lead to long delays in initiating human subjects research projects. The Yale University IRBs utilize a regulatory review process involving pre-review of the initial protocol submissions, to ensure quality and completeness prior to the formal review by the fully convened IRB or expedited reviewer. This regulatory review process often includes back and forth communication with the research team, sometimes through multiple cycles, focused on clarifications, suggested revisions, and consent form changes. We recognized that there may be repeated problems that recur across multiple protocols, leading to sometimes prolonged delays in the approval process. As part of a project team working under a National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) grant supplement, Yale IRB leadership participated in sharing of best practices with a partner institution in an attempt to improve quality and efficiency of IRB operations. As a result, we undertook a number of projects that aim to shorten the time protocol submissions spend at the regulatory review stage. Shortening this time frame should reduce the overall turn-around time for approval of new protocols. We adopted a 100-day project plan that focused on empowering researchers to create a better quality product - a well written protocol application that satisfies IRB expectations – prior to its initial submission to the regulatory reviewer.

Description of Program/Research

Methods
The 100-day project involves four stages: 1. systematically identifying the areas of the protocol application that appear to be the most problematic for researchers; 2. conducting focus groups with members of the research community to brainstorm on solutions to remedy the identified problem areas in the protocol application; 3. rewriting the identified areas of the application to ensure clarity of the questions being asked based on the outcome of focus groups; 4. analyzing the turn-around time of the regulatory review stage and the amount of back and forth communication exchanges with the investigators prior to and after the implementation of the revised application. Each IRB staff member was asked to retrieve their correspondences with the research staff regarding the last three research protocols that they had regulatory reviewed. The Committee letters requesting minor revisions were also analyzed. Each requested revision was correlated with the question on the protocol application. Out of almost 200 inquiries sent to research staff requesting revisions or clarifications, four areas of the protocol application were found predominantly problematic. These areas generated the highest number of issues. The members of the research community – including principal investigators, study coordinators and co-investigators - were invited to participate in focus groups concentrating on the four areas of the protocol application that prompted the most requests for changes. The focus groups are currently ongoing. Once completed, the feedback from the focus groups participants will result in revision of the protocol application. The improved version of the form will be implemented in June.

Results
Data regarding the time required for regulatory review has been collected since February 2009. Unsatisfactory findings led to initiation of this project. The protocol application will be revised to incorporate the changes recommended by the research community in June 2010. The time required for regulatory review will be collected for three months following the implementation of the revised application and compared to data collected prior to the revisions. Data from our partnering institution and preliminary data suggest that revising the most problematic questions in the application will reduce the overall time to approval by the IRB and decrease the number of times that IRB staff communicates with the investigators prior to the research project's official review. Additionally, initial focus groups demonstrated the discrepancy between the IRB staff’s expectations of the protocol application and the researchers’ perception of what the form requires. Feedback from the focus group participants regarding their
experiences in the brainstorming session was very positive and indicated that improvement initiatives, such as this project, are well-received and appreciated.

Future Use
Once the protocol application is revised and implemented and this 100-day project proves successful, similar efforts will be launched to improve the clarity of the remaining questions on the application and other forms, such as the request for continuing review or amendments. The scope of this initiative can also be expanded to other areas of the IRB internal operations. Furthermore, this 100-day rapid cycle project provides a model for quick and efficient quality improvement (QI) and education initiatives that can be easily implemented in other IRBs struggling with scarce resources, demanding volumes of work and time constraints. It allows the institutions to use the resources available to them at relatively small costs. A rapid cycle QI project can be managed by the IRB staff as part of their professional development. The research communities are also helpfully responsive to IRB efforts to develop more efficient practices, as they are the most affected party by any institutional deficiencies and will benefit the most from successful improvements.
Remedies for the Top 10 Stalls in the IRB New Protocol Submission Process

*University of Indianapolis*

Donna B. Konradi

**Topic:** IRB Operations

**Problem/Issue Statement**

A factor that contributes to predictable delays and stalls in the IRB review process is "premature protocol submissions." A submission is labeled as "premature" when one or more of the following problems exist: the protocol is missing essential elements, the presented information is not clear, and/or the presented information is internally inconsistent and contradictory.

**Description of Program/Research**

Because of concerns expressed by investigators regarding the length of time from initial protocol submission to final IRB approval, the IRB Chair, Staff, and Institutional Official conducted an internal audit. One of the audit purposes was to describe factors that contribute to delays and stalls in the review process. A factor significantly linked to many delays and stalls was "premature protocol submissions." A submission was labeled as "premature" when one or more of the following problems existed: the protocol was missing essential elements, the presented information was not clear, and/or the presented information was internally inconsistent and contradictory.

Two factors contributed to the decision to focus an intervention on reducing the incidence of premature protocol submissions. First, we noted during our internal audit that premature submissions take longer to progress through the IRB review process. Multiple communications from IRB staff are needed to compile the required documents and complete the protocol application. Then, during the IRB review process, more time is consumed as reviewers seek clarification for conflicting and confusing information. It was our hope that improving submissions maturity would decrease the length of time required for review and decrease investigator frustration. Second, committee members agreed that it takes them additional time to review premature submissions. Because our IRB hosts an annual educational forum, we decided to use this familiar strategy to help investigators improve the protocol submission "maturity." We titled this forum "Remedies for the Top 10 Stalls in the IRB Review Process" (emphasizing the word "remedies"). The first purpose was to describe common problems that lead to delays in the review process. The second purpose was to describe remedies for resolving common problems. The third purpose was to provide credible and accessible resources. Each session was co-presented by the IRB Chair and an IRB Committee member. Most committee members attended at least one session and contributed to the dialogue. At the beginning of each session, the desire for collaboration and discussion was emphasized. Both sessions were well attended and participation was active and respectful. Forum materials and the presentation slides were posted to the IRB website and have been downloaded by faculty for classroom instruction. An adapted version of the Remedies for the Top 10 Stalls program is scheduled for presentation to a national audience in a 1 hour Webinar format. Our IRB will track protocol review time to assess the impact of this programming intervention.
Leody A. Bojanowski, DNP, RN, CIP

**Topic:** IRB Operations

**Problem/Issue Statement**
There is a lack of information on any systematic investigation of the exempt approval process at academic research universities in the U.S. The problem that is being addressed in this study is the knowledge-gap about conventional practices representing an institution’s implementation/interpretation of the regulations governing exempt research studies.

**Description of Program/Research**
Institutional Review Boards (IRB) at academic research universities are entrusted with providing human research subjects protections oversight by reviewing the potential risk of harm to subjects in studies submitted for IRB review and approval. Current regulations do not require IRB approval for most minimal-risk research studies and thus are exempt from IRB review. A review of research policies from academic research universities and surveys of 31 IRB Administrators were employed in the fall of 2009 to gather data describing the patterns of exempt review procedures and to identify common issues or problems associated with the review and approval of exempt research. In the data analysis phase, variables compared among IRBs were: (a) the size of the research portfolio, and (b) descriptive information about the process (method of submission, designated reviewer, turn-around time for approval, etc.) Most of the universities surveyed use an electronic submission system for exempt studies. A majority of the IRB administrators surveyed disclosed that approximately 10% of the research studies submitted yearly are exempt from IRB review, and only 39% described a one-week turn-around-time for approval. Although IRB administrative staff members do most of the review of exempt applications, the IRB Chair/designee is responsible for final approval at the majority of the institutions surveyed. Common problems identified by both IRB administrative staff and the Investigators included: (1) Investigators not being able to differentiate between Exempt Research and Non-Human-Subjects research; (2) Investigators submitting exempt studies that do not meet any of the exemption criteria for approval and (3) Complaints about the complexity and length of the exempt application process. With good training and education of University department heads or designees, exempt research may not need to be submitted to the IRB or the IRB Administrative Office, thereby reducing the likelihood of unnecessary scrutiny of these minimal risk studies resulting in a more expeditious approval process.
Rocky Mountain Tribal Institutional Review Board Beginnings

Montana Wyoming Tribal Leaders Council
Allyson Kelley; Cheryl Belcourt; Gordon Belcourt

Topic: IRB Operations

Problem/Issue Statement

Tribal Institutional Review Boards are gaining momentum in Montana and Wyoming; however, the process of developing a Tribal IRB and the incorporation and development of existing IRBs and cultural resources is not always clear. The RMTIRB seeks to integrate Tribal Knowledge with existing IRB protocols and resources to create a truly unique Tribal IRB. How is this done and what steps are necessary to create a Tribal IRB?

Description of Program/Research

We are in our first year of designing the Rocky Mountain Tribal IRB. Two years ago the Billings Area Indian Health Service notified the Montana Wyoming Tribal Leaders Council that the Institutional Review Board (IRB) would in effect, dissolve due to the retirement of the IRB Chair. Upon being informed of this situation, the Board of Directors (comprised of Tribal Chairs & Presidents) decided that the Montana Wyoming Tribal Leaders Council should take over this function and create the Rocky Mountain Tribal Institutional Review Board (RMT-IRB). A resolution was approved by our Executive Board and two small grants provide for some training and infrastructure support for this process. • The IRB will first support any Tribal IRBs but will provide application review when projects involve two or more Tribes in Montana and or Wyoming. • Tribes may also designate or direct applicants to the RMT-IRB in lieu of their own Tribal Review. • The IRB will serve as a universal IRB and include non-health related research. • IRB members will include community members, scientist, non-scientist, and topic area experts as needed by application. There are two part-time program staff who have designed the RMTIRB creation process and implementation. To date the evaluation has been summative in that we have sought the input from Tribal Leaders and Tribal Health Directors to determine the necessary steps for the RMTIRB. We have also sought known IRB experts to evaluate our progress and our program design. Finally, we have learned that there are many unique considerations for Tribal IRBs and their interaction with state, local, federal, and national funding agencies.
Safety Monitoring of Multicenter & Multinational Sites in an Investigator Initiated Study: The Dual Role of the Investigator/Sponsor Necessitates a Data Safety Monitoring Tool that Recognizes the Added Responsibilities of the Coordinating Site and Includes a Remote Monitoring Plan
Halia Melnyk

**Topic:** QA/QI

**Problem/Issue Statement**

The Investigator-Sponsor of a study has the overall responsibility for the conduct of all participating sites. In addition to being the Principal Investigator (PI) of the lead site, the Investigator-Sponsor also serves as the coordinating center for all sites. When these sites include multinational sites, safety monitoring assumes an added layer of complexity due to regulatory differences and coordination of monitoring; and is confounded by pace of enrollment and increased budgetary/resource needs related to oversight of and travel to distant sites. A comprehensive and flexible data safety monitoring template, outlining how monitoring will be coordinated amongst sites, is a valuable tool that would assist Investigator/Sponsors in their dual role and enhance compliance with governing IRB requirements and GCP.

**Description of Program/Research**

The template should include a mechanism for the reporting of adverse events in accordance with both local and international IRB’s, and conformity of international sites with those requirements of the governing IRB and sponsor. A procedure for remote monitoring in the event that budgetary/resource constraints, or the slow pace of enrollment, preclude travel to distant sites, should be included. Such a plan would include the method for the transmittal of protected health data as well as ensuring that the informed consent form includes language informing the subject that the coordinating center will have access to this data. The responsibilities checklist would complement the data safety monitoring tool, and should include a list of investigative sites and all documents that the governing IRB requires be submitted to them. Such items would include local IRB approvals, both initial and continuing, copies of consent forms, regulatory documents, progress reports, and patient screening/enrollment logs. It should also include the mechanism for communication of protocol changes, personnel changes, data safety reports, unanticipated problems, and interim data analyses, from the coordinating center to the sites and vice versa. Once the plan is approved by the governing IRB it should be communicated to all sites, as part of the site initiation visit. The overall monitoring body will evaluate progress of study at the frequency outlined in the plan. Governing IRB will evaluate adherence upon continuation review. Successful templates may be posted on IRB website.
Streamlining Ethics Review of Multi-center Public and Population Health Research Involving Humans: A Pilot Project

Pierre Deschamps, LScR, BCL, CM; Laurel Evans, BA, LLB; Lorraine E. Ferris, PhD, LLM; Jaime Flamenbaum; Ronald J. Heslegrave, PhD; Mireille Lacroix, BSocSc, LLB, LLM; Peter Monette, PhD; Diann G. Nicholson; Raphael Saginur, MD, FRCPC; Josie B. Sirna, MSc; Donald J. Willison, ScD; Tom Wong, MD, MPH, FRCPC; E. Louise Yazdani, RN, MA, Grad Cert. PHRAM

**Topic:** Streamlining ethics review

**Problem/Issue Statement**

In response to the recognized need for streamlining the ethics review of multi-centre research involving humans, a steering committee composed of research ethics board (REB) officials, researchers, academics and funders, as well a Public Health Agency of Canada Facilitation Team, worked to develop and pilot such a process.

**Description of Program/Research**

When a proposed study is to be conducted in more than one institution (“multi-centre research”), the conventional process requires researchers to submit separate applications for research ethics review to each institution – after which each institution conducts its review independently. During SARS, researchers and research ethics boards (REBs) recognized that this process tended to produce duplication, over-review, pressure on REBs for unduly quick response, and researcher frustration. Therefore, Canadian REBs have been working individually and collectively to develop rapid, robust processes for the protection of human subjects. The recent H1N1 pandemic further increased interest in a process that can be used across Canada.

**Description**

The streamlined process was developed through consultation. Implementation generally involves: • One application to one REB; • Access to that application by all concerned REBs through a secure website; • Inter-REB sharing of comments prior to review; • “Lead” REB-hosted initial review, with teleconference participation by other concerned REBs; • Posting of “Lead” REB decision documents on the secure website; • Concurrence by other REBs, or decision following expedited or full board review, then posting of decision documents; • Ongoing monitoring by all REBs. The process can be adapted according to user needs and preferences.

**Results**

The process reduces workload of co-investigators and their REBs; and allows direct communication among REBs prior to and during review – thereby, potentially enhancing the review process. Each participating REB retains its autonomy, decision-making authority, accountability to its institution, and liability. Impacts/Next Steps: Under this process, research participants can be protected in a more uniform and timely fashion in accordance with Canadian ethical and legal standards - particularly during emergencies. Evaluation at the end of the two year pilot will help the Steering Committee decide whether the streamlined process is a step towards a long term solution, or a solution in itself.
Streamlining the Process of Conducting Facilitated Reviews

Case Cancer IRB
Jennifer C. Scharf-Deering, MA, CIP; Lori L. Karpinecz, MA; Mariesa L. Malinowski, BA, CIP

Topic: IRB Operations

Problem/Issue Statement

The Case Cancer IRB is enrolled in the National Cancer Institute’s (NCI) Central Institutional Review Board (NCI CIRB) program. A primary goal of the NCI CIRB is to reduce the administrative burden for local IRBs, investigators and research staff. During 3 years of participation, we identified the following obstacles to review, submission and records requirements for IRB and investigators:

- Ill-defined facilitated review procedures were ineffective and duplicative;
- Increasingly limited resources including staff and filing space; and
- Unclear boundaries of local IRB responsibilities

Description of Program/Research

The Case Cancer IRB developed local procedures for conducting facilitated reviews, as per the NCI CIRB recommended local procedures and from an effort to establish a “best practice” model for other Comprehensive Cancer Centers. The revised procedure better identified the NCI CIRB as the IRB of Record, eliminating the need for investigators to submit continuing reviews and amendments that do not alter consent forms. Submission of paper documentation available through the NCI CIRB website became unnecessary. The Case Cancer IRB eliminated a local “approval letter” and developed a monthly notification of NCI C-IRB approved protocol acceptance that was found acceptable by both the NCI Clinical Trials Support Unit (CTSU) and Cooperative Groups. The program evaluation is on-going. The Case Cancer IRB Administrative staff examined current practice and recommended corrections to ineffective and redundant processes. A draft of the standard operating procedures was sent to primary research users. This draft was then reviewed by a multi-institutional Cancer IRB Advisory Group and Case Cancer IRB Committee. We plan to develop more robust internal office processing guidelines and tools. These include on-going purging of historic paper records that are maintained and available via NCI CIRB website. We will also target education and training about NCI CIRB initiative to less frequent users and created a NCI CIRB user feature on Case Cancer IRB website. Implementation requires ability address unforeseen concerns. Sites should develop mechanisms to address transition of files to revised process. Flexibility is needed to overcome unexpected obstacles.

Additional Information

Creating a facilitated review procedure has reduced delay from time of IRB review to notification and issuing of acceptance. Compliance with to NCI CIRB approved materials has improved by allowing IRB staff/Members to focus on local context review issues, including consent forms. The new procedure has also reduced potential lapses in local IRB approval due to administrative processing delays and increased potential for improved compliance using current consent forms.
Student Research Requirements and the need for Faculty Training
North Carolina A&T State University
Dr. Karen Smith-Gratto; Mrs. Donna H. Eaton

Topic: QA/QI

Problem/Issue Statement
At North Carolina A&T State University more and more students are involved in original research that involves human subjects. The university has moved from primarily a teaching institution to a Research I institution, requiring that faculty members both conduct their own research and guide students through original research projects. As a result, many faculty members are unfamiliar with the requirements for a faculty member advising student research. This has resulted in student applications that are poorly done because of a lack of oversight. These problems include: a mismatch between the original research proposal and the IRB protocol; poor descriptions of the research design or missing research design information; incomplete IRB applications; submissions which lack timeliness for expected graduation dates; and lack of resubmissions when changes are required.

Description of Program/Research
Two steps were taken to remedy the problem. First a policy was developed to explain the faculty advisor’s responsibilities and the consequences for students and faculty when the policy is not followed. Next an educational workshop targeting programs which require class research projects, theses and dissertations was developed. The training provided for faculty within these areas is designed to reflect the types of studies that are conducted within those disciplines. For example, in teacher education, examples of K-12 research studies are used. The training includes: basic IRB training; the faculty advisors’ responsibilities with regard to human subjects research; how to help the student develop the IRB application based upon the proposal; how to check the IRB protocol to insure appropriate information and completeness; understand the programmatic issues that can lead to non-compliance and adversely impact the student’s knowledge of how to conduct human subjects research properly. The policy was completed during the Spring 2010 semester and the training will be given early in the Fall 2010 semester. Faculty members who attend the workshops will be surveyed about the workshop. The evaluation will consist of comparing previously submitted protocols to those submitted after training. A table describing problems found on the protocols will be compiled in order to facilitate a comparison of the protocols. Graphs indicating the number and type of errors before and after training will be developed from the table. Once the comparison is made, gaps in the training can be identified and the training adjusted.
Surrogate Consent for Research: Practical Concerns One Year Later
University of Medicine & Dentistry of New Jersey
Donna Hoagland, LPN, BS, CIP, CIM, CCRC; Susan Torok-Rood, RN, MSJ, CCRP, CIP; Paula Bistak, RN, MS, CIP, CHRC; Julie Kligerman, Esq.

Topic: IRB Operations

Problem/Issue Statement

In 2008, the New Jersey State Legislature passed the ‘Access to Medical Research Act’ as a supplement to Title 26, allowing for the first time in the State the use of certain surrogate consent procedures for enrollment of study participants with impaired capacity to consent. Although access to and consent for research with impaired adults, is a national concern, New Jersey is one of the few states with legislation specifically designed to address this complex issue.

Description of Program/Research

Speakers will include an attorney and IRB administrators from the University of Medicine & Dentistry of NJ who will cover the following: The current state and federal regulatory framework for informed consent with impaired adults, what we learned from the experience in New Jersey, useful tools and solutions to apply to research with impaired adults, what may lie ahead.
Synchronizing CITI Training Across Regional Institutions
*Cincinnati Children's Hospital Medical Center*
Mina P. Busch, MS, CCRP

**Topic:** Research Education

**Problem/Issue Statement**

Researchers involved in the conduct of research at multiple area institutions (universities, academic medical centers, and community hospitals) had to complete multiple, and often redundant, training curricula to satisfy the requirements of each individual institution. Each institution was already utilizing CITI (Collaborative Institutional Training Initiative) programs, but there was no reciprocity among the institutions leading to duplicate administrative tasks and learner efforts.

**Description of Program/Research**

Our efforts created a common, shared curriculum that satisfies the requirements of several regional entities. We began with establishing a common goal. Then, we established multi-institutional focus groups to evaluate the various curricula and suggest shared programs. After plans were assembled, this went to all the institutions for approval before a new CITI entity was created to accommodate the completions of the consortium. Detailed plans for a successful rollout were developed and shared. The program completed rollout in 2009 and has since been expanded to allow for the RCR (Responsible Conduct of Researchers) requirements as well as Community Physician Access.

This has proved to be a very useful tool for IRBs who can now easily verify training completion of all PIs (not just those at our base institution). It streamlined/consolidated training and communication efforts among member institutions. It has reduced overall training requirements for those doing research at multiple institutions. It served as the refresher training for all institutions that had originally deployed CITI 2-3 years ago. It positions all institutions for continued compliance through common refreshers (to be deployed in 2011). With over 1400 institutions now using CITI, we've established a strong common training requirement that is universally supported. We have already shared our progress with another "Academic Health Center" but foresee how this synchronization could benefit other institutions in similar circumstances.

**Additional Information**

We also recognize and thank the CITI staff in supporting us through this endeavor.
The Consciously Designed IRB
Aspire IRB
Currien MacDonald

Topic: IRB Operations

Problem/Issue Statement
Traditional research protection programs have evolved out of institutional pressures; they are created and supported only as required, building on the years or decades before. With the increase in industry-sponsored research, the ability for a rationally developed, ethical and self-supporting IRB became possible. From a human subject's protection point of view, what would an ideal IRB look like?

Description of Program/Research
This poster presents each component required by the multiple factors and its proposed solution. For example, the regulatory requirement for non-scientific is represented as a basic foundation, not a minority, and describes the logical rationale for this construction. It presents each component as a part of a cohesive whole that has its primary intention fully appreciated at its origin.
The Establishment of an IRB Service Recognition Program (ISRP): A CDC Approach

Centers for Disease Control and Prevention (CDC)
Constance M. Bonds, MPA, CIP; Natalie Brown, MPH; Denise Marshall, BS; LaShonda Roberson, MPH;
Barbara DeCausey, MPH, MBA

Topic: IRB Operations

Problem/Issue Statement

The Centers for Disease Control and Prevention (CDC) policy prohibits Institutional Review Board (IRB) members that are employed by CDC from receiving monetary compensation for their service. To address this issue, CDC’s Human Research and Protection Office has developed an IRB Service Recognition Program (ISRP) that highlights the important contributions IRB members make during their tenure of service.

Description of Program/Research

The CDC IRBs critically review research protocols that involve human subjects to ensure that adequate protections are in place for research participants and also make recommendations to improve submitted protocols in order to better serve those individuals volunteering for research studies. These reviews cannot be accomplished without competent individuals that feel valued for their time and commitment to this important process. The ISRP is intended to recognize CDC employees for their IRB service and to demonstrate the value of the employees’ contribution towards the protection of human subjects in research.

Development, Design, and Implementation of Program

Upon drafting a standard operating procedure for recruiting CDC employees for IRB service, we recognized that there was no program in place to recognize the contribution of CDC employees who voluntarily participate on the IRB. IRB service requires a CDC employee to contribute his or her time in the execution of responsibilities and tasks associated with serving on the IRB, in addition to their primary employment role and responsibility. In most cases, this voluntary work is done during off hours such as evenings and weekends. During the summer of 2009, an informal survey of three other federal agencies determined there was no formal process in place to recognize IRB members for their service. Recognizing the need to acknowledge CDC employees for their important contributions to the IRB process, an ISRP was developed and implemented in the fall of 2009. The recognition program includes: Recognition of departing member during their last official IRB meeting, Certificate of appreciation and An acknowledgement letter from the CDC Institutional Official thanking the IRB member for their service. Three retiring IRB members have been recognized thus far through this program.

Suggestions for the Future or for Implementation

The ISRP is still new and evolving. Although agency policy does not allow CDC employees to receive monetary compensation for their IRB service, IRB service can now be acknowledged by the ISRP at CDC. Looking forward, IRB service may also become standardized criteria that could be considered during employee performance evaluations. In addition, future benefits to IRB members may consist of offering Continuing Education Credits to members as they complete IRB related education.

Conclusions

Feedback for the newly implemented ISRP has been positive from IRB members and CDC staff concerning the recognition of IRB members. To identify and retain IRB members with enough expertise to review protocols and represent a number of disciplines is a continual process that is only enhanced by having a recognition process in place to reward its members for their service. Other institutions whose policies do not allow financial compensation to recognize and reward IRB members may find this program beneficial.
The Headquarters, U. S. Army Medical Research and Materiel Command Human Research Protection Program

Department of Defense (DOD) Directive 3216.02 requires that DOD Components (e.g. Army, Navy) have a mechanism to provide headquarters-level oversight of research involving human subjects that is conducted or funded by the DOD. This Directive gives the DOD components latitude to develop appropriate oversight mechanisms. Directive includes additional protections above and beyond the Common Rule requirements, and all research conducted, funded or otherwise supported by the DOD must comply with the directive. Each DOD component has a unique process for accomplishing headquarters-level review. The United States Army Medical Research and Materiel Command (USAMRMC) is a Major Subordinate Command of the United States Army Medical Command and serves as the backbone of the joint biomedical research and materiel community. Central to the mission of the USAMRMC is the conduct and management of research to enhance, protect, treat and heal the war fighter on point for the Nation. The USAMRMC has six research laboratories and funds extramural projects that support the core missions of the USAMRMC as well as congressional interest programs. USAMRMC’s research portfolio ranges from drug and device development research in areas such as infectious disease, combat casualty care, post traumatic stress disorder, and traumatic brain injury, to cutting edge research in oncology, composite tissue transplantation and regenerative medicine. The USAMRMC is committed to adhering to the highest ethical standards in the conduct of research and the protection of human research participants. The USAMRMC supports human subjects research in over 1330 institutions in 39 countries. The majority of this research is extramural. Most extramural institutions are not familiar with the DOD requirements, therefore a mechanism to ensure compliance is necessary.

Description of Program/Research

This poster will focus on the USAMRMC Headquarters Program of human subjects research oversight of intramural and extramural research. The USAMRMC Office of Research Protections, Human Research Protection Office (HRPO), is responsible for ensuring compliance with Federal, DOD and Army regulatory requirements for over 3446 active human subjects research protocols conducted, funded, or otherwise supported by the USAMRMC. The USAMRMC ORP HRPO manages the human subjects protection ethical review, approval, and continued oversight of all extramural and intramural research. In 2005 the HRPO began a data driven initiative to streamline processes and move towards a dynamic risk based approach to human subjects protection regulatory compliance oversight. This poster will review incremental process improvements for both intramural and extramural research and describe the impact these changes have made in both review metrics and protection of human research participants. This poster will describe the current HQ USAMRMC Human Research Protection Program administered by the HRPO which includes initial protocol review and approval, education, quality improvement, compliance oversight, addressing investigator and institutional non-compliance, and participant outreach. We will describe our improved methods of outreach to funded institutions, investigators, and IRBs to assist them with navigating smoothly through the required headquarters-level review process in an efficient manner while ensuring protection of participants. DOD and Army unique requirements will be discussed. A multi-modal approach for continuing oversight of intramural and extramural protocols will be outlined, including human research protection program site visits, investigator reporting requirements to the HRPO, and routine audits at the time of continuing review.
The Infectious Disease Institutional Review Board (ID IRB), a Centralized Approach to Review and Approval of Infectious Disease Research within the U.S. Military
Victoria Zajack; Trueman Sharp; Bridget Arnwine; Margaret Pickerel; David Tribble; Richard Levine

**Topic:** IRB Operations

**Problem/Issue Statement**

The ID IRB was formed with the goal of providing a more efficient, alternate pathway to the complex multi-site and multi-service system that often hinders timely implementation of important military-based infectious disease clinical research.

**Description of Program/Research**

The ID IRB exists within the Uniformed Services University (USU) in Bethesda, Md. and functions under the auspices of the University's Office of the Vice President of Research. The ID IRB provides ethical and regulatory oversight to the Infectious Disease Clinical Research Program (IDCRP), a collaborative multisite clinical research network effort between the DoD and the National Institute of Allergy and Infectious Disease (NIAID). An agreement between the Surgeons General of each military service, DoD Health Affairs, and the President of USU has granted human subjects protection oversight to the ID IRB. The ID IRB functions in many ways as a traditional IRB, with monthly full Board meetings, and with exempt and expedited research reviewed administratively. There are fundamental differences in the composition of this IRB, the conduct of the meetings and also with the submission process. The ID IRB membership is comprised of individuals from the participating DoD medical commands and NIH, including members from Naval Medical Center in San Diego; Brooke Army Medical Center and Wilford Hall Medical Center in San Antonio; Naval Medical Center Portsmouth, VA, as well as local medical commands. Meetings are conducted at USU but many of the participating members attend the meetings via conference call. Protocols are developed through the IDCRP, receive rigorous independent scientific review (SR), pre-IRB regulatory review, and are then submitted to the ID IRB. In the past, protocols would have been submitted to each participating site’s SR, IRB and service-specific HQ administrative review, frequently taking several months to even years before project implementation. This centralized approach has shortened this process by many months. An ongoing challenge is fostering effective communication and coordination between the ID IRB and the local sites. The consensus among researchers and program leadership has been that this streamlined process has greatly facilitated multisite infectious disease clinical research, addressing current high priority health threats to military personnel.
The Role of National Institutional Review Boards (IRBs) in Protection of Research Participants: Experiences of the Medical Research Council of Zimbabwe (MRCZ)

Resign Gunda; Sithembile Ruzario; Rutendo Gutsire;

**Topic:** Protection of Research Participants

**Problem/Issue Statement**

The MRCZ houses the National Ethics Committee (NEC) whose main mandate is the scientific review and ethical approval of all medical research. In Zimbabwe, MRCZ offers research ethics and GCP training to all researchers including those currently involved in HIV Research. As NEC, we also monitor HIV prevention and treatment studies. The role of research ethics in biomedical research cannot be over-emphasized. The research community as a whole suffers when even a few investigators ignore the basic principles of ethics. The consent process should go beyond the written consent form. Researchers need to understand that there should be follow-up and continuous education of the participants throughout the research. There is need for researchers not to over-emphasize on potential benefits to participants. It is worthwhile for researchers to find innovative ways of describing research to participants. MRCZ is therefore taking a leading role in creating research ethics awareness among researchers.

**Description of Program/Research**

Researchers, IRB members, medical students and research teams were trained in research ethics and good clinical practice (GCP). After the training activities, MRCZ carried out routine inspection of all ongoing studies to ensure that researchers are adhering to their protocols and complying with ICH-GCP and other international guidelines. In year 2009, 700 researchers were trained in Research Ethics and Good Clinical Practice (GCP). Those trained were made aware of the current versions of international guidelines on the ethical conduct of research. These guidelines include ICH-GCP, CIOMS and Helsinki Declaration. The training workshops that have been carried out in the last 3 years have greatly increased awareness of research ethics amongst researchers. There has been significant improvement in the informed consent process as researchers in Zimbabwe are increasingly becoming aware of the importance of protecting the rights and welfare of research participants. In research design of protocols, researchers have the responsibility to ensure that priority is given to the rights and welfare of research participants. The experiences of MRCZ in creating research ethics awareness will be shared.

**Additional Information**

Usability Study of IRB Website at Texas Tech University: A Two-Stage Model

Texas Tech University, Lubbock, Texas
Donna Peters, CIP; Rosemary Cogan, Thomas Barker, PhD.; Joyce Carter, PhD.; Kristina Butler, BS

Topic: IRB Operations

Problem/Issue Statement

Information on human subjects research including procedures and forms is available on a designated website provided by Texas Tech University. However, faculty, student and staff users were frequently calling the IRB Office for answers to questions that were addressed on the website. Collaborating with faculty in the English Department at Texas Tech University, the IRB became the “client” to a classroom of students. This relationship provided practical experience with technical opportunity to the students as a class project as well as, an expert review of a website for the IRB; a definite win-win situation. The current study follows up on this work to build a two-stage model of usability analysis.

Description of Program/Research

In the fall 2007, Dr. Thomas Barker, TTU English Professor, arranged to work with the IRB and conduct the first stage of a usability study of the TTU IRB website during his semester course. Findings of the study included the presence of unclear language, difficulty in navigation, inability of users to know where to start, and a poorly organized site. A final report was submitted to the IRB presenting recommendations that would improve the usability of the website. In 2010, a new TTU IRB website was launched which incorporated these usability study recommendations. In May 2010, Dr. Joyce Carter, TTU English Professor, arranged to conduct the second stage of the usability study of the IRB website as a class project. The IRB again became the “client” and findings and recommendations will be submitted in a final report. Analysis of the second usability study will measure usability from a user’s perspective. The task development measure will be used to test the website. A comparison of the new IRB website to the previously studied website will be conducted to see if recommendations from the first study had any impact on the current study. A rapid application design approach will be used based upon the previous website reviewing the changes implemented into the new website and the affect of these changes on end users. The data collected will be used in a longitudinal study as the new website changes with the second study recommendations. Results of the study will be forwarded to the webmaster for discussion and website improvements. This two-stage study model could be replicated in many institutions to test the usability of IRB websites.
Using Metrics to Make an Impact in a Human Research Protection Program

University of Texas Health Science Center San Antonio
Dawn A. Lantero, PhD; Joseph O. Schmelz, PhD, RN, CIP, FAAN; Jenice N. Longfield, MD, MPH

**Topic:** IRB Operations

**Problem/Issue Statement**

In today's intense regulatory environment, using metrics to make an impact is especially important for investigators and the research enterprise. The University of Texas Health Science Center San Antonio (UTHSCSA) used metrics to identify specific targets for improvement in the Institutional Review Board (IRB) and for exploration of the role of the Research Subject Advocate (RSA).

**Description of Program/Research**

Establishment of a career ladder and adding staff with IRB certification credentials were justified by using staff vacancy and turnover rates. The career ladder reduced the vacancy rate from 36% in 2007 to 0% in 2008 and 2009, and decreased staff turnover rate from 50% in 2007 to 15% in 2008 to 0% in 2009. The IRB organizational structure was transitioned from a vertical reporting chain to a horizontal structure with more functional teams which increased staff flexibility. Additional metrics depicting complexity of protocols and the quality of review processes were targeted to increase efficiency of the IRB approval process. Complexity of protocols was defined as the type of review required for approval; thus, only protocols requiring full board approval were reviewed by a convened board, while all other protocols were reviewed by the newly hired expedited reviewer. The result was a decrease in time from submission to approval for all studies. Specifically, the time for expedited review decreased from 70 days in 2006 to 15 days in 2009, while the time for full review decreased from 120 days in 2006 to 88 days in 2009. For those studies requiring approval by the convened board, pre-reviews examining the ethical, regulatory, and scientific merit were performed by IRB board members and IRB staff. This resulted in significantly fewer studies being tabled compared to the number of studies approved during the convened board meetings. The ratio of new studies approved to tabled studies was 7:1 in 2007, 20:1 in 2008, and 43:1 in 2009. A database to explore the types and source of referrals to the Clinical Translational Science Award (CTSA) RSA was developed. The types of issues addressed to the RSA, and both the number of contacts and the position of the person to whom the referral was made for resolution, helped portray areas of participant or research team concerns. This data will be utilized to improve research study initiation procedures and to develop a research subject advocacy program for exportation to CTSA inpatient and outpatient research sites of the UTHSCSA.
VA Central IRB: A Unique Model of Centralized Review with Both Central and Local Accountability

Department of Veterans Affairs
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Topic: IRB Operations

Problem/Issue Statement

The Department of Veteran Affairs (VA) has 109 medical facilities located throughout the United States that can perform human subjects research. Each of these facilities has its own IRB, uses another VA’s IRB, or uses a University affiliate IRB as an IRB of record. The VA, through the Office of Research and Development (ORD), directly funds approximately $500 million of research a year. Many of these studies involve multiple sites in which it could take over a year to get a study reviewed and approved at each local VA site. In addition, the Principal Investigator (PI) had to track numerous versions of the protocol, consent forms, and other documents that were often personalized to each site’s IRB. This process demanded a significant amount of resources and complicated the ability of the study team to properly oversee the study. Also, the local IRBs often did not have all the required expertise to review some of these large, complicated studies.

Description of Program/Research

The VA Central IRB was developed in 2008 to improve human research subjects protection in ORD multisite studies by providing consistent expert ethical and scientific review while still ensuring local issues were addressed. A second objective was to improve the efficiency of the reviews. As of May 1, 2010, the VA Central IRB has become an IRB of record for 84 of the 109 VA facilities that can perform human subjects research and has reviewed 28 studies involving 269 sites. A site is counted separately for each study in which it is participating. A detailed Memorandum of Understanding (MOU) sets forth the duties and responsibilities of the local VA facility, the Veterans Health Administration Central Office, and the VA Central IRB. The VA Central IRB model involves a two-step application process incorporating a local comment period. This process has been revised and refined over the initial first two years of operation and is in the process of being streamlined even further. This model has generated interest nationally, and numerous presentations have been given to various groups. An application for accreditation was submitted in April 2010 and a significant expansion in study volume is projected to take place over the next year. A second VA central IRB is in the process of being developed to handle the expected workload. By enhancing the efficiency and consistency of the review process, this model has the potential to facilitate faster translation of research results to the clinical environment.
What to Do With 40 Tons of Old But Irreplaceable Data – An Ethical Framework for Evaluating Later Research with Previously Collected Data

The United States Army Aeromedical Research Laboratory

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Topic: Regulations and Guidelines

Problem/Issue Statement

In 2007, the US Army Aeromedical Research Laboratory (USAARL) acquired 40 tons of biodynamic data, medical images, and photographic data from previous military injury prevention research conducted between 1971 and 1996. Today, the dataset represents an invaluable resource from which new research questions can be answered without exposing additional participants to physical testing. However, we are faced with the challenge of determining if and how this vast dataset may be used while protecting the original expectations of the human volunteers and their personally identifiable data. In the absence of specific regulatory guidance, we used the Belmont principles to guide our process of converting the vast dataset into a data repository for future research.

Description of Program/Research

For the first Belmont principle—respect for persons, we inventoried the data and carefully examined the original research protocols, ethical committee approvals, and signed consent forms from all original studies. The original signed consent forms from all but approximately 10% of the volunteers, which were interspersed throughout the vast dataset, were reviewed, and we concluded that the consent process appeared to be valid, meaningful, and voluntary. To address the second Belmont principle—the principle of beneficence, we considered both the potential for benefit to military and civilian knowledge and data repository governance to minimize risks. Since data collection was previously completed, potential harm is now limited to possible breaches in confidentiality. Therefore, we are currently writing a standard operating procedure (SOP) that details where and how data are kept, who may access data, what approvals must be obtained prior to access, the process for data de-identification, and repository oversight and monitoring. Additionally, the SOP will ensure the data are used in a manner consistent with the participants’ original intent. The final Belmont principle—justice—led us to consider two key aspects: ownership of data and the potential for distribution of future research results. Volunteers originally consented to their data being used and kept by the military for research purposes. Consistent with this intent, results of future uses of this dataset will continue to benefit the military and civilian populations. With an inventory of the original data and volunteer research documentation and the preparation of a SOP, we determined that future biodynamic research with this dataset was consistent with volunteers’ intent and the Belmont principles. An advantage of our process is that the framework can be applied to evaluate the potential for later research uses of any dataset.
When “Minimal Risk” is Not Enough- A Discussion Addressing the Need to Minimize Risk in Pediatric Research
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**Topic:** Ethics and Risk Assessment

**Problem/Issue Statement**

Pediatric studies, particularly those sponsored by pharmaceutical companies, may be directly adapted from protocols intended for adults without taking sufficient steps to minimize risks to children. This discussion will focus on two studies that were not approved, not because of an unacceptable level of risk associated to a specific procedure, but because of a failure to minimize the overall risks for pediatric subjects.

**Description of Program/Research**

The first study proposed a parallel group, randomized controlled, dose-escalation Phase II trial to compare a starting drug with placebo for subjects aged 10-19 years, with newly diagnosed Type 1 diabetes mellitus. Dose-response data was lacking for children prior to study initiation and was not included as an objective of the trial. The IRB concluded there was inadequate justification for the dosage proposed in the protocol and the data gathered would not provide guidance for subsequent trials. In addition, a fixed dosage was proposed rather more typical pediatric dosing (based on weight or body surface area). The IRB had substantial concerns about overdosing smaller subjects who would receive much higher relative dosages than larger children.

Further, the sponsor proposed a role for the DSMB in decisions regarding individual subject’s diabetes management even though diabetes management was not a study intervention nor was control of diabetes a primary endpoint. The IRB concluded that this exceeded the DSMB’s authority and increased risk to subjects.

The second study required all subjects, whether on active drug or placebo, take part in intensive PK testing (24 hour, in-hospital) at the week 6 visit. The IRB considered the overall risks of the procedures to be a minor increase above minimal risk making the study potentially approvable under §46.406 and §50.53. However, the IRB concluded that risks to participants, particularly the risks of intensive PK testing, had not been minimized because alternative designs (e.g., obtaining PK data during the open-label portion) could achieve the same objectives without subjecting placebo participants to risk without direct or indirect (scientific benefit).

**Conclusions**

The decision to disapprove the research in both cases presented hinged not upon the level of risk presented by the procedures themselves, but on failure to minimize risk. In both cases, the IRB concluded that alternative study designs could have achieved the same objectives with less risk. IRBs should ensure that industry-sponsored clinical trials minimize risk to the greatest extent possible by using procedures and designs that are sensitive to the special needs of children as research subjects.