Scientific Poster Abstracts from the
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A Pilot Study for Informing Consent: Forming a multimedia prototype for enhancing participant comprehension of clinical research trials
Yukari Takata, Doctoral Student

Topic: Informed Consent

Problem/Issue Statement

The informed consent for research process is significant to medical research because it must communicate complex and serious information to participants with various needs in clinical trials. It also embodies an ethical legacy that tells of some of the most abject crimes against individuals in modern history. Therefore, the medical research community is keen on improving its method of delivery. However, despite a large body of literature suggesting ways to improve the informed consent process and research supporting the value of multimedia tools for promoting patient comprehension, the medical community has lagged in the fusion and creation of such materials. Based on Albert Bandura and Everett Roger's theories on behavioral/technological adoption, I propose that this adoption lag is largely because instruments for developing multimedia materials have not been simplified and streamlined into daily activities of healthcare practitioners and clinical researchers. Seeing that the informed consent process, more specifically the form, is both a critical resource for study participants and a mandated document for researchers to create, it is crucial that software is developed to essentially automate the multimediafication process of informed consent materials and ultimately, improve participant comprehension.

Description of Program/Research

The overarching hypothesis for this project posits that the adoption and creation of multimedia resources by the medical community will increase if essential designing software is packaged and molded in a manner that fits within established procedures and practices at clinical institutions. Toward this end, this pilot study sought to answer the following research questions: How proficient are researchers at utilizing computer technology? How confident are they in their ability to create multimedia-based materials? Where, in their daily procedures, could the multimediafication process of informed consent materials fit? While keeping in mind the needs of their participants, in what ways would researchers improve their informed consent resources?

Methods

The pilot study was conducted with researchers involved in a specific clinical trial at the University of Florida's Clinical and Translational Science Institute (CTSI). The researchers' computer proficiency and associated confidence levels were assessed using the Technology Proficiency Self-Assessment tool developed by Margaret Ropp. In the same study, two focus groups were conducted to gather suggestions for developing a meaningful Electronic Informed Consent (eIC) prototype for this particular study.

Results

Results for this pilot study shed light on the basic computer proficiency levels of researchers involved in a specific clinical trial at the University of Florida and their recommendations for their study's eIC prototype. Additionally, a review of literature looking at simple yet meaningful digital tools suggests that the eIC prototype may resemble the web pages of the popular medical site, WebMD.

Limitations

The current study is the first of several aimed at simplifying the multimediafication of informed consent resources by developing task-specific software for clinical researchers. Therefore, its scope and application is intentionally narrow at this time. Furthermore, participant computer literacy levels and attitudes toward online learning will also need to be taken into consideration as this research project progresses.

Next Steps
An initial eIC prototype will be developed by September 2010 in collaboration with the University of Florida’s Digital World Institute. Further development will be directed through researcher and participant feedback as the project progresses; conduction of case-controlled studies to evaluate the eIC prototype’s effectiveness in facilitating participant comprehension; and, finally, implementation of an institution-wide survey to evaluate institutional and researcher attitudes toward the eIC prototype and their intentions to adopt the conceptualized software based on the eIC prototype as a sample product.
Adolescent Perspectives on Informed Assent for an HIV Vaccine Trial
Diane Blake, MD; Celeste Lemay, RN, MPH; Margaret Kearney, PhD, RN; Kathleen Mazor, EdD

Topic: Informed Consent

Problem/Issue Statement

Once a promising candidate HIV vaccine is developed and tested, adolescents will be asked to volunteer for clinical trials. Although enrolling adolescents will be critical, little is known about their perceptions of the real risks and benefits of participation. Our goal was to identify misunderstandings and misconceptions that could prevent adolescents from being able to provide truly informed assent.

Description of Program/Research

Methods

Study Design: Qualitative descriptive study. Measures: Eight focus group interviews (4 male and 4 female groups) were conducted with young people, aged 15-17 years old, using a semi-structured interview guide. Digital recordings were transcribed verbatim. Analysis: Textual data were categorized using qualitative content analysis techniques. Two investigators (DB and CL) coded data into categories of responses based on research questions and spontaneously offered comments. The percentage of agreement was calculated and the coding scheme was revised after each round until >90% agreement was achieved.

Results

Concepts that teens identified as the most difficult to understand included: placebo, randomization, false positive HIV test, and how a vaccine works. Teens had little or no knowledge regarding how a vaccine works, with many teens believing vaccines are therapeutic rather than preventative. Many participants believed that an algorithm based on the participant’s health or relationship with the investigator would be used to decide whether an individual received placebo or test vaccine. Many had difficulty understanding why standard HIV antibody tests might provide a false positive result for participants receiving the test vaccine. Focus group participants would want to receive information about the side effects of an HIV vaccine and whether any previous testing had been done on animals or humans before making a decision about trial participation. Participants thought that some teens entering a vaccine trial would be less likely to use condoms because they would assume they were protected from HIV by the study injection in spite of counseling to the contrary.

Conclusions

Many vaccine trial concepts were difficult for teens to understand. Attention will need to be directed toward developing effective ways to explain these concepts in any future HIV vaccine trial assent. Special effort should also be paid to effectively communicating the many reasons why a study injection may not protect one from contracting an HIV infection. The participants in our study demonstrated an interest in understanding key features of a vaccine trial before making a decision about participation.
Adolescents’ Preferences for Timing of Parental Involvement in the Research Assent Process
Pediatrics, University of Massachusetts Medical School
Celeste Lemay, RN, MPH; Margaret Kearney, PhD, RN; Kathleen Mazor, EdD

Topic: Informed Consent

Problem/Issue Statement

Parental permission and adolescent assent are both required for the participation of a minor teen in a study that involves more than minimal risk. Little is known about teens’ perspectives on the time point during the assent process at which parents should be involved. Our goal was to explore adolescents’ preferences for how and when they would want to share decision making with their parents and the reasons for their preferences.

Description of Program/Research

Methods
Study Design: Qualitative descriptive study. Measures: Eight focus group interviews (4 male and 4 female groups) were conducted with young people, aged 15-17 years old, using a semi-structured interview guide. Questions about shared decision making were part of a larger study exploring adolescent perspectives on assent. Digital recordings were transcribed verbatim. Analysis: Textual data were categorized using qualitative content analysis techniques. Two investigators (DB and CL) coded data into categories of responses based on research questions and spontaneously offered comments. Agreement was calculated and the coding scheme was revised after each round until >90% agreement was achieved.

Results
Adolescents’ opinions varied regarding when to involve parents in the assent process. Some teens would want to decide independently whether or not to participate prior to obtaining their parents’ permission. Reasons included not wanting parents to influence the adolescents’ decisions or lecture them regarding information in the assent, not wanting information in the assent to reveal anything to the parent about the teen’s behaviors, and wanting to be independent and treated like responsible persons. Several of these adolescents would want to lead their parents through the assent in order to influence the parents’ decisions. Other teens would want to make the decision together with their parents. These adolescents believed their parents would know the teen and his/her medical history better than the teen would, could explain things the teen didn’t understand, were trustworthy and reliable, and had collaborative relationships with the adolescents.

Conclusions
Participants in these focus groups wanted to be active participants in the decision making process for research participation but held differing opinions about the timing of parental involvement in the assent process. Adolescent preferences should be considered out of respect for their autonomy and to assure that adolescent assent is intentional and authentic.
An Assessment of the Expectations and Anxieties of Clinical Trial Research Participants in Zimbabwe, concerning Post Trial Care

Mrs. Melody E. Phiri-Shana; Ms Rosemary Musesengwa; Ms Sithembile Ruzario; Mrs. Rutendo Zinyama-Gutsire; Mr. Resign Gunda; Mrs. Estere Mutero

Topic: IRB Operations

Problem/Issue Statement

The impetus for this survey was an interest in assessing the views of research participants in clinical trials on post trial care. The survey explored through a questionnaire the expectations and anxieties of research participants who were about exit clinical trials so as to enable researchers and regulators to address concerns of participants before their exiting studies.

Description of Program/Research

The main objective of the survey was to evaluate and understand the views of research participants who were about to exit research studies. The questionnaire was administered to fulfill the following specific objectives:

- To conduct assessment of the participants willingness to be enrolled in the National ART program;
- To ensure understanding that research has is only for a limited time;
- To highlight to researchers areas that need addressing concerning participants before their exiting studies.

A total of 30 research participants who were about exit studies were interviewed. An overall of 100% response rate was achieved. Most respondents indicated that they were skeptical, whilst a few were indifferent of being moved to the National Program. Respondents sighted that the care they would receive there would be very different and they had developed relationships with the study staff and this made it very hard for them to move on. Respondents also highlighted that the National Program was overwhelmed and they were not certain if they would access the drugs and tests they required. Most respondents highlighted understanding that research was for limited time and that this was included in the consent forms.

Respondents highlighted that their respective studies had taken time to explain to them during the informed consent process that research was for a limited time and they would be rolled over to the National Program upon exiting the study. When comparing the standard of care in the National Program and that in clinical studies, respondents unanimously acknowledged that the care and treatment received were very different and lamented that their studies were coming to an end, as they had grown used to high standard of care, with access to drugs, vital tests, for example CD4 counts and specialist doctors. Some respondents suggested that researchers should seek more funding and do more studies so they would continue accessing the high standards of care. Based on this survey researchers worked tirelessly with the Ministry of Health and Child Welfare in setting up an Opportunistic Infections (OI) Clinic at the University of Zimbabwe-Clinical Research Centre (UZ-CRC) site. The clinic was specifically set up for patients that had exited studies. This helped alleviate fears among participants as they were accessing care and drugs from a familiar environment even thought this was under the National ART Program.

Additional Information

In conclusion, continued treatment of clinical trial participants with nationally licensed medicines at the end of a trial is required for the continued care of patients. It is therefore, important that governments, ethics regulators and researchers work together to ensure that participants exited from clinical trials have access to drugs after studies end and that issues of past trial care are written in the protocol and are agreed on and approved by the IRBs before studies commence.
And Justice For All: Equitable Access to Benefits and Protection from Harm in HIV/AIDS Research with Vulnerable Populations
Rachel V. Boschma-Wynn; Christiane Brems, PhD, ABPP; Gloria D. Eldridge, PhD; Staci Corey, MS; Mark E. Johnson, PhD.

Topic: Special Populations

Problem/Issue Statement
The federal system for protecting research participants is designed to ensure that no class of individuals is denied equitable access to potential benefits of research, nor unduly or disproportionately exposed to its potential harms. Given the nature of incarceration, special challenges emerge when considering issues of potential harm and equal access to benefits of research for with individuals detained in correctional settings. Equitable distribution of harm and access to benefits of research for incarcerated individuals is further complicated when the research involved deals with potentially stigmatizing issues such as HIV/AIDS. The current study explores challenges of ensuring equitable access to benefits and protections from harm when conducting HIV/AIDS research in correctional settings.

Description of Program/Research

Methods
A nationwide sample of 92 individuals with experience or knowledge in the conduct or oversight of HIV/AIDS research in correctional settings participated via telephone in a 60-90 minute semi-structured key informant interview. Participants included 30 researchers, 15 prison administrators, 15 research ethicists, 16 IRB members and 16 IRB prisoner representatives who were identified through project members, national consultants, literature reviews, internet searches, and snowball sampling. Interviews were audio-recorded, transcribed and analyzed using NVIVO software for qualitative data analysis. This work focuses on justice related to potential harms and benefits of research.

Results
Data analysis indicated several potential barriers to implementation of just, ethical HIV/AIDS research in correctional settings. Foremost among access impediments were federal regulations designed to protect incarcerated research participants. Although developed to protect incarcerated individuals from harms, these regulations are more commonly perceived as blocking access to the potential benefits of research. Additionally institutional barriers and less than informed IRB approval procedures for HIV/AIDS research in corrections were identified as possible barriers to justice for incarcerated individuals. Recommendations are offered for researchers in a multitude of settings and systems in which participants’ access to research benefits; protections from research burdens and harms; and capacity for rendering voluntary, informed consent are not equal to those for the general population.

Conclusions
This study is an important step towards addressing challenges of HIV/AIDS research in correctional settings and supporting growth of this type of research. Additional research is needed to further expand the understanding of barriers and recommended practices. Future research should include a wider range of respondents experienced in HIV/AIDS research with incarcerated populations.
Are Principal Investigators Distinguishing the Boundaries Between Practice and Research?

NYU School of Medicine
Joy Jurnack, RN, CCRC; Helen Panageas

Topic: Ethics and Risk Assessment

Problem/Issue Statement

In academic medical centers, being able to distinguish between the role of doctor/patient and researcher/subject is important to the overall success of research. If this distinction becomes blurry there could be a significant impact on the equitable selection of subjects, the validity of the science and the potential new treatment options. In this study we aim to determine whether this distinction is being made. We believe that doctors/researchers are having difficulty making this distinction.

Description of Program/Research

A web based anonymous survey of 600 researchers/physicians at NYU School of Medicine and its affiliates will be distributed in May 2010. The samples size includes all human subject researchers at NYU SoM and its affiliates. Respondents will be allowed 2 months to complete the survey. We will analyze the data collected using frequency distribution methods to determine how many people answered the survey questions. Results will be available in August 2010. We anticipate possible limitations to the study if response numbers are limited. To minimize this possible limitation, researchers will be made aware of the survey on a weekly basis through various forms of advertising and inter- institutional communications; i.e. Newsletters, NYU Medical Center 'Doctor Talk' Radio show, and Posters. Once the survey is complete, the data collected will be used to develop education and training programs targeting PI Responsibilities and PI Certification programs.
Assessing Management of Pregnancy in NIH Clinical Trial Protocols
Dr. Maria Rita Machado Vieira; Pamela Stratton, MD, NICHD; Christina Gonzalez; Shannon Liu, NICHD; Asma Idriss, CTDB; Barbara Karp, MD

Topic: Special Populations

Problem/Issue Statement
The 1993 NIH Revitalization Act required that women of childbearing potential (WOCPS) be included in clinical trials. This study assesses whether written protocol documents address what will happen if pregnancy occurs during research participation.

Description of Program/Research

Methods
Intramural clinical trials posing more than minimal risk to WOCPS were reviewed to determine if they 1) monitored for pregnancy and 2) stated what would happen if a woman became pregnant. Studies were categorized as to whether they posed ongoing risk to women (for example, taking a teratogenic drug) or episodic risk (for example, a single procedure involving radiation exposure). Each protocol and consent was reviewed by two independent reviewers and reconciled with NICHD Clinical Trials Database software.

Results
496 on-site clinical trials met the inclusion criteria. 79% of the studies posed ongoing risk and 21% posed episodic risk. Most studies (57% ongoing, 73% episodic) excluded pregnant women. 93% of studies with ongoing risk and 95% of those with episodic risk included pregnancy testing. 80% of studies with ongoing risk and 45% of those with episodic advised or required contraception during participation. Fewer than half of the written protocol documents stated what would be done if a woman became pregnant while in the study. 33% of ongoing-risk studies and 17% of episodic studies stopped the research intervention or withdrew the woman from the study in the event of pregnancy. Follow up visits and assessment of pregnancy outcome were provided in 21% of studies with ongoing risk and 7% of studies posing episodic risk.

Conclusions
WOCPS are being included in clinical trials, and most studies that pose risk to a fetus or the pregnancy appropriately exclude pregnant women and provide pregnancy testing. Many require or recommend contraception. Even so, some women do become pregnant during participation. Investigators should prepare for such a contingency. Discontinuing study intervention is important; pregnancy counseling would also be advisable. Rather than withdrawing pregnant women from a study, investigators should consider following them throughout pregnancy to assess its outcome. Since very few medications are FDA approved for use in pregnancy, information on the outcome of women who become pregnant during studies can provide information crucial to society and to participants’ health.

Next steps
Our results highlight the need for a standardized approach for management of women who become pregnant during research participation to ensure the safe inclusion of WOCPS in clinical research.
Communication Problems among IRB Stakeholders: An Exploratory Study
Dr. Darla D. Beaty

Topic: Ethics and Risk Assessment

Problem/Issue Statement

Institutional Review Boards (IRBs) have emerged as arbiters of ethical research with human participants during the past 35 years. Researchers and IRBs charged with protecting research participants must assure that consent is given with full understanding of their choices. Communication difficulties exist among stakeholders - researchers, IRB members and human participants. This study explores and describes current problems and proposes ways to improve communications. Investigation focused on the interactions and strategies of three primary research stakeholders. Data were gathered from online surveys with 161 participants. SPSS 17 was utilized for analysis. Responses from two focus groups (one which was conducted at PRIM&R 2009) and individual interviews were coded for themes.

Description of Program/Research

Three aims drove the analysis. The first aim was to identify methodologies currently recommended by IRB members and used by researchers to assess consent capacity. Study results found a significant difference in the 69% of IRBs who recommend cognitive assessment and the 41% of researchers who use a strategy. There was a significant difference in the strategies they used, with methods being varied among the IRBs and researchers. The second aim was to explore communication between Institutional Review Boards and researchers about the key issues of the research. Focus groups and individual interviews revealed themes of Conflict, Power and Responsibility for Cognitive Assessment. The third aim was to explore communication between researchers and potential participants about the key issues of the research. Results indicated that the consent form that is relied on by IRBs is not relied on by researchers, as they use informal communication.

Additional Information

This exploratory study can serve as a basis for further research regarding the most effective methods for communication among stakeholders. It may inform policies which govern involvement of individuals with decisional impairment.
Current knowledge in proper Management of Human Subjects Research and IRB procedures among research-related personnel working in two Peruvian cities: A pilot study
K. Pamela Corzo; Victor E. Gonzaga; Carlos A. Sanchez; Joel M. Montgomery

Topic: International

Problem/Issue Statement
Human subjects research (HSR) has been rapidly expanding among many institutions throughout Peru. In response to this surge, many Institutional Review Boards (IRB) have been created but mostly in the capital city of Lima, where training opportunities are also concentrated. This could mean opportunities for HSR training for research-related people (RRP) working outside of Lima may be insufficient to respond to the demand. Knowledge of IRB procedures is critical to obtaining approval and facilitating communication between the investigators and IRB personnel. Two international courses on bioethics were held in the cities of Cusco and Trujillo and RRP were invited to attend. We sought to identify and explore the research topics in which these individuals were experienced and to assess their knowledge about IRB procedures.

Description of Program/Research

Methods
A survey was conducted to all individuals attending both ethics training courses. Demographic information, data about experience conducting scientific research, knowledge and previous experience about ethics issues were collected. Descriptive statistical analysis was conducted using STATA.

Results
One hundred and twenty questionnaires were collected (Response Rate = 100%). Participants included non-physician health care professionals (49%), physicians (39%), social scientists (9%) and administrative personnel (3%). The locations at which the participants worked included Public Health Facility (Hospitals, health centers, etc.; 43%), universities (35%), independent research groups (13%), and NGOs (1.8%). Seventy-eight percent of the participants indicated that they had experience conducting research studies but only 23% required an IRB approval. Eighty-two percent of participants reported they had never submitted a study for publication, only 19 (23%) had submitted a publication, of these 13.2% were physicians, 6% other health professionals, and 4% social scientists. Furthermore, 61% of participants reported no previous bioethics training, while 39% had previous training. Similarly, questions related to management of Human Use Research Studies were only responded by 18% individuals.

Conclusions
Our findings suggest that there is a lack of experience regarding the administrative procedures for protocol submission among persons working in two cities outside Lima. Physicians are more likely to publish than other RRP. Similar ethics courses should be routinely conducted outside of the capital in order to include populations that don’t have the availability of travelling to attend courses in the capital and who have other background different other physicians. Thus, this situation may be common in similar settings in other developing countries and our conclusions may be potentially applicable to other areas of the world.
Custom Case Report Forms More Completely Assess Adverse Events During Drug Clinical Trials: Evaluation by the RADAR (Research on Adverse Drug events And Reports) Project
Dr. Dennis P. West; Jennifer Lagman; Christina H. Georgopoulos; Dr. Sigmund A. Weitzman; Laura Qualkenbush; Athena T. Samaras; Dr. Steven M. Belknap

Topic: Risk Assessment

Problem/Issue Statement
Methodological and process flaws often impede IRBs in their efforts to interpret and act upon clinical trial adverse event reports. This is of particular concern in cancer clinical trials due to the high toxicity of cancer drugs and the difficulty of distinguishing drug toxicity from progression of cancer or comorbid conditions. Clinical trial adverse event reports rely on an unstructured, largely subjective assessment by the investigators, despite evidence that such assessments are unreliable. Efforts to simplify, standardize, and assure completeness of adverse drug event (ADE) reports are likely to improve the IRB’s ability to monitor the conduct of clinical trials and protect human subject safety. In this study, we evaluated whether use of a precise taxonomy and scales, drug-specific case report forms, and a validated causality instrument improved identification and reporting of ADEs occurring during clinical trials of cancer at an NCI-designated cancer center.

Description of Program/Research

Methods
We used custom case report forms specialized for disease–drug–toxicity to abstract data related to ADEs reported for bevacizumab at an academic center. The Common Terminology Criteria for Adverse Events (CTCAE 3.0) was used to specify the taxonomy of the adverse event and to grade its severity. The Naranjo ADR Probability scale was used to assess causality.

Results
Of the 51 subjects who experienced bevacizumab reported ADEs during the study period, the use of custom case report forms identified five events that were not identified by the standard method. (p < 0.00001) These events included two cases of hemorrhage, two cases of thromboses, and one case of severe hypertension. Data completeness for causality scoring was more complete with the custom case report forms. ADE severity scoring was similar for the two methods.

Conclusion
Accuracy of ADE reporting is significantly enhanced through use of custom case reports designed to elicit data elements that are essential to describe adverse events, assess severity, and define causality.

Limitations
Limits of this study include a relatively small sample size and the evaluation of one institution only.
Desired Characteristics for an IRB: How Do IRBs at One Institution Measure Up?
St. Joseph Mercy Health System
Darlene Wahlberg; Bonita Singal; Dr. Richard Lampman; Trista Koehler

Topic: IRB Operations

Problem/Issue Statement

Introduction The Institutional Review Board (IRB) is a regulatory body entrusted to protect the welfare and privacy of research subjects. In this capacity, a major responsibility of an IRB is to assure protection of the rights of human subjects participating in research; and secondly, to maintain organizational interests related to local, state and federal research regulations. Purpose The purpose of this study was to obtain objective measures from researchers regarding their perceptions of the functions of the two monitoring IRBs at SJMHS in order to determine discrepancies between the services provided versus the perceived value of the services delivered.

Description of Program/Research

Methods
A validated Institutional Review Board Researcher Assessment Tool (IRB-RAT) containing 90 survey questions was administered to staff members at SJMH, an independent academic center. Results the return rate for the IRB-RAT survey was 31%. The responders indicated that the way an IRB conducts reviews, communicates decisions and postulates fairness were the most important characteristics valued. The domain of upholding the Human Rights of research participants, ranked only fifth for the responders. The rank order for the importance of the domains studied was: Interactional Justice, Absence of Bias, Procedural Justice, Pro-Science Sensitivity, Protection of Human Rights, Formal Functioning, and Competence, with Outreach being last. For each domain the value characteristics delivered by the IRBs matched those desired values of the researchers. Most important services to the responders were timeliness and constructive reviews, and efficient communication.

Results
Results of this survey suggest a discord may exist between the IRB, whose mandate it is for human subject protection, and the researcher’s priority of respect, timeliness of reviews and open communication. Educational outreach results suggest that the IRB policies and informational forms provide enough direction as to regulatory guidance to the researcher.

Conclusion
To avoid antidotal judgments, IRBs should consider periodically administering validated surveys to gain knowledge regarding the actual services provided with respect to perceived services experienced.
Effects of Implementing a Post-Graduate Course on Research Ethics; A Policy Study from Cairo University
Dr. Rehab A.A. Abdel Hai, M.D.; Professor Mohamed Hassan. Hussien, M.D.; Professor Henry Silverman, M.D.

Topic: International

Problem/Issue Statement

Background: There is universal agreement, in the scientific community, that training in ethical aspects of research is essential to conducting high quality ethical research. In developing countries, training in research ethics is available on a very limited scope. Aim: Assess the effects of implementing a curriculum in research ethics at the Faculty of Medicine, Cairo University – Egypt.

Description of Program/Research

Methods
During the academic year 2009 – 2010, six hours of research ethics were developed and introduced in the research methodology course for postgraduate students at the Public Health Department of the Faculty of Medicine, Cairo University. This was done over a period of 3 weeks. We used a 24 item questionnaire at the beginning and end of the course to assess the effects of training. Questions evaluated knowledge of participating students on research ethics principles, functions and operations of Institutional Review Boards (IRBs), and ethical reasoning.

Results
All trainees were registered postgraduate students, of which the majority were females (84% - n=21) and had obtained a previous M.Sc. degree (76% - n=19). A total of 25 participants completed the pre-test and only 21 completed the post-test. The mean score for knowledge of the principles of ethics rose from 3.61 ± 1.46 at pre-test to 5.28 ±0.75 at post-test; maximum 7 points with P= 0.001. Ethical reasoning, as assessed by questions on two case studies, also showed similar improvements from 3.33 ± 1.33 to 4.83 ± 0.38 and from 4.50 ± 0.79 to 4.94 ± 0.24 out of 5 points for case1 and 2 respectively. These findings were statistically significant (P ≤ 0.02). An overall score for all questions on the questionnaire showed a marked improvement in overall score from 17.56 ± 3.07 to 21.61 ± 0.98 with P < 0.001.

Conclusions
An initial evaluation of the effects of training showed that trainees’ knowledge and ethical reasoning skills markedly improved after the course. However, we still need to assess long term effects. Next Steps: It is recommended that this curriculum continue to be implemented within the public health postgraduate course as it provides a prospect of capacity building in research ethics.
“Ethics is for Human Subjects Too”: Understanding Participant Perspectives on Responsibility in Health Research
Prof Susan M. Cox; Prof Michael McDonald; Ms Sara Hancock

Topic: Experiences of research participants

Problem/Issue Statement

Despite the considerable energy devoted to ethical review, little attention is given to understanding the experiences of those who volunteer as human subjects. Why and how do they decide to participate in research? Is research participation viewed as a form of social responsibility or are participants motivated primarily by more individualistic benefits? Beyond respect, what if anything do research participants feel they are owed for their participation? And what do they feel that they themselves owe the researcher and/or the research?

Description of Program/Research

Drawing on in-depth individual interviews conducted with a diverse sample of 41 participants in health research, this paper focuses on participant perspectives on responsibility in research. Highlighting the range of ways that participants describe their involvement in research and commitments to being a ‘good’ subject, we develop a typology of narratives that sheds new light on the diverse meanings of research participation. These narratives are not mutually exclusive or prescriptive but are, rather, best viewed as ideal types that typify a set of circumstances and axiological leanings. The understanding these narratives contribute is salient to enhanced appreciation for the social good that research participants contribute. It also has significant implications for researchers who seek more human-subject centered approaches to research recruitment and retention and research ethics boards who strive to apply a subject-centered perspective in evaluating the ethics of research protocols.
Evaluating the Quality of Information about Alternatives to Research Participation in Oncology Consent Forms
David B. Resnik; Dan Patrone; Shyamal Peddada

Topic: Informed Consent

Problem/Issue Statement
A careful consideration of the alternatives to research participation is an essential element for making an informed choice on whether to enroll in a biomedical research study. While there is general agreement on the importance of informing prospective subjects about alternatives to research participation, little research has been conducted on the quality of consent forms. The purpose of this study was to attempt to assess the quality of information about alternatives contained in informed consent documents in randomized oncology controlled trials.

Description of Program/Research

Methods
The consent forms were drawn from the sample used in our previous study of alternatives, which was obtained by requesting consent forms from Phase II, III, or IV non-pediatric U.S. randomized oncology controlled trials registered at Clinicaltrials.gov. 104 consent forms were reviewed. We developed a scoring system to measure the quality of the alternatives discussion and coded all of the consent documents using this system, based on the U.S. federal regulations, and the reasonable person standard in law and ethics. We gave a consent form a score of “0” if it contained no discussion of alternatives; a “1” if it mentioned that alternatives exist but did not list or describe any alternatives; a “2” if it listed or described alternatives; and a “3” if it listed or described alternatives and provided some information that could be helpful in deciding whether to choose one of the alternatives. To ensure reliability, two of us independently scored all of the documents according to the measures we developed.

Results
57.7% of informed consent documents scored a 2 for their discussion of alternatives, 32.7% scored a 3, 4.8% scored a 1, and 4.8% scored a 0. 52.9% of the documents were model forms (i.e. forms developed by a research group for a multi-center trial) and 47.1% were local (i.e. forms approved by a particular IRB). 53.8% of the studies were publicly funded, and 46.2% were privately funded. The average age of the consent forms was 2.4 years (i.e. beginning of 2005), and the average percentage of the document devoted to the discussion of alternatives was 2.4%.

Conclusions
Our study indicates that there is room for improvement concerning the discussion of alternatives to research participation in informed consent documents in oncology randomized controlled trials. Though most of the documents in our study met the minimal disclosure standard found in the U.S. federal regulations, less than a third met the reasonable person standard, a widely accepted principle endorsed by the common law and various ethics guidelines and documents. There was a statistically significant difference between the alternative discussions in local and model forms (P= 0.0014). The alternatives discussions in local informed consent documents were more likely to receive higher scores than those in model consent documents, with an odds-ratio of 3.5 to 1. One possible reason why local forms scored better is that local IRBs have more information about the availability of local alternatives than research committees that draft model forms. Limitations First, our results may not generalize to all clinical research because we only sampled consent forms used in oncology trials. Second, since our study focused on consent documents, it is possible that investigators may use other forms of communication to discuss alternatives to research participation, such as meeting with subjects to answer questions about the research. Next steps To conduct additional studies on the discussion of alternatives to research participation, by interviewing research subjects and investigators.
Evaluation of informed consent understanding among subjects with low educational attainment in Brazil
Dr Edson D. Moreira, Jr.; Leonardo B. V. Souza; Raimundo C. S. Neves; Elizabeth G. Duarte; Dr Edson D. Moreira, Jr.

Topic: Informed Consent

Problem/Issue Statement

A major challenge of the informed consent process in developing countries is to assure subject's understanding about the informed consent basic components, particularly among those with low educational attainment. Here we report results of a survey to measure comprehension of informed consent in Brazil.

Description of Program/Research

Methods
A consecutive sample of 236 subjects aged 18 or above, participating in two cancer prevention trials was surveyed. We used a self-completed questionnaire comprised by three open questions and seven statements which were classified by the subjects as true or false. All items regarded basic components of the informed consent such as: study objectives, potential benefits and risks, and participants' rights and obligations. The questionnaires were filled in by subjects who agreed to participate in the trials, right after they had discussed and signed the consent. Data were collected from Mar/2003 to Sep/2005. Descriptive statistics were provided to measure subjects understanding of the informed consent. Data analysis was performed using the software Stata ® (version 10.0).

Results
We enrolled 120 (51%) men and 116 women (49%), the mean age was 32 years, 78% had High-school education or less, and only 2% had attended College. All individuals were participating in a clinical trial for the first time. Most volunteers were able to identify correctly study objectives and potential benefits, 90% and 83%, respectively. A sizeable proportion (30%) could not identify potential risks of study participation, and only half acknowledged there could be no benefit from enrolling in the trials. The vast majority understood the right to withdrawal from the study without prejudice (96%) and that they would have no cost to participate (94%), but a lower percentage (70%) understood the random allocation of the study intervention. All subjects reported being comfortable about giving consent, and none felt pressured by any site personnel to enroll in the trials.

Conclusions
In general, the understanding about basic components of the informed consent in this population of low educational attainment was good, particularly, in regard to study objectives and participants rights. However, knowledge about potential study risks and the random nature of allocating the intervention was poor. These items should be the focus of strategies to improve subjects understanding of the informed consent. Further studies to assess the quality of the informed consent process and to identify determinants of good understanding in subjects from developing countries are warranted.
Evaluation of the Quality of Informed Consent in Clinical Researches
Ihnsook Jeong

Topic: Informed Consent

Problem/Issue Statement

This study aimed to assess the quality of informed consent process by measuring subjects' understanding of informed consents of their studies.

Description of Program/Research

This study aimed to assess the quality of informed consent process by measuring subjects' understanding of informed consents of their studies. Convenience sample of 188 subjects aged 20 and above participated in bioequivalence studies by Inje regional clinical trial center, Busan. Study instruments were self-reported questionnaire, which were modified Quality of IC (QuIC) developed by Joffe et al (2001), and Informed Consent Questionnaire-4 items (ICQ-4) developed by Guarino et al (2006). Data were collected from Feb to May, 2007, and analyzed with descriptive statistics to assess the quality of informed consent process, and t-test, X2 test, and paired t test to identify correlates of increased understanding of informed consent using SPSS version 14.0. Mean QuIC objective knowledge score (QuIC-A) was 68.7 points (max: 100points) and perceived (subjective) understanding (QuIC-B) 78.7 before participating in clinical trials, and 68.7 and 80.4 after participating in clinical trials respectively. General quality of informed consent (ICQ-4) was measured after participating in clinical trials, and score was 78.3points (max: 100points). Higher objective knowledge (QuIC-A) was associated with age (25 years old and above, p=0.043), and education (college and above, p=0.001), Higher QuIC-B score was associated with past experience participating in clinical trials (p=0.028), and memorization of date signed informed consent (p=0.037). Quality of informed consent process is not favorable and lower than other studies in the US and Australia. Strategies to improve subjects understanding of informed consent need to be developed.
Factors Influencing Satisfaction with Transition to Electronic Submission
Jessica L. Rakauskas, B.S.; Henian Chen, MD, PhD; Mary Cataletto, M.D., MMM

Topic: IRB Operations

Problem/Issue Statement

BACKGROUND: The transition from paper to electronic submissions has allowed clinical research to move forward by optimizing access to submissions, ensuring completeness, security, privacy, record preservation and facilitating auditing and compliance. This study was undertaken to evaluate factors influencing user satisfaction following transition to electronic submissions in the research community of a university affiliated medical center.

Description of Program/Research

Methods
An IRB approved scientific survey was conducted among members of the research community at our institution, which was approximately evenly divided between MD/PhD s and non physician/regulatory personnel. Out of 140 surveys, eighty were completed and included in the study, yielding a 57 % response rate. Sixty eight percent of respondents were women; 32.9 % men. Responses were analyzed by means of a chi square test or Fisher exact test. Logistic regression analysis estimated effects of possible predictors on satisfaction. Results are expressed as percentage and odds ratio (OD). All analyses were performed with the use of SAS software, version 9.2.

Results
Women reported a higher degree of satisfaction with the transition to electronic submissions as compared with men although neither group supported a return to paper (91.7 vs. 79.2 %). Female gender was associated with lower computer knowledge (45.1 vs. 66.7%) however both groups were equally likely to enlist IRB staff support (70.1 vs. 70.8%). Respondents with both clinical and research responsibilities were significantly less satisfied than other groups (62.5 vs. 89.6 %, OR = 6.62, P=0.033). Additional factors which were found to be significantly and independently related to satisfaction were timeliness of response from IRB support staff ( 96.7 vs. 80.0 %, OR = 6.625, P=0.004 ), easier tracking system ( 90.6 vs. 63.61 %, OR=5.524, P=0.015 ) easier communication ( 92.2 vs. 75.0 %, OR = 3.917, P= 0.041 ), less paper ( 90.6 vs. 63.6 %, OR = 5.524, P = 0.015 ) and overall time savings ( 94.3 vs. 68.2 %, OR= 7.778, P= 0.002 ).

Conclusions
Overall, 81.3 % of all subjects reported that they were either satisfied or very satisfied with the transition to electronic IRB submissions. IRB administrative support was utilized in all groups regardless of age, gender or educational background. Although women had a lower estimation of their computer knowledge and skills, they expressed a significantly higher degree of satisfaction with the transition to electronic submissions to the IRB. Time savings and IRB administrative support services are significant factors influencing satisfaction.
High re-consent rates don’t mean they don’t care: participants’ views about submission of existing study data to dbGaP
Evette J. Ludman, PhD; Susan B. Trinidad; Stephanie M. Fullerton; Leslie Spangler; Monica Fujii; Wylie Burke

Topic: Informed Consent

Problem/Issue Statement

In the interest of advancing research and the translation of basic scientific findings into clinically useful applications, Federal policy strongly encourages researchers to submit de-identified study data to the database of Genotypes and Phenotypes (DbGaP). While such deposition can, and should be, addressed in the informed consent process for new studies, no clear consensus exists about when permission (or re-consent) is ethically required for the submission of previously collected data. In particular, little is known about the preferences of research participants with respect to the submission of their study data to dbGaP.

Description of Program/Research

Methods

Alone among the eMERGE sites, the Group Health IRB determined that submitting study data to dbGaP from an existing cohort (the Adult Changes in Thought [ACT] Study, a prospective cohort study of Alzheimer’s and dementia, started in 1994) required participants’ re-consent. A combination mail and in-person consent process was used, with 86% of cognitively intact participants giving permission for their data to be shared. We then contacted 400 of those who had consented by mail for a telephone interview to ask for their views about the re-consent process and whether they felt it was necessary.

Results

A total of 365 participants (91%) completed the survey. Respondents identified altruistic goals and strong trust in Group Health as key factors in deciding to allow dbGaP submission. Even though respondents were willing to allow their data to be shared, 90% considered it important that they were asked for permission. Respondents did not favor opt-out consent (27% saw this as completely unacceptable, 28% as somewhat unacceptable) or notification of submission after the fact (47% completely unacceptable, 20% somewhat unacceptable). No notification and no consent was also viewed as unacceptable by the majority of respondents (54% completely unacceptable, 16% somewhat unacceptable).

Conclusions

High re-consent rates do not imply that participants do not wish to be given the choice about dbGaP submission. This study population is well disposed toward research participation, the research institution, and the investigators; participants nonetheless wanted to be asked for permission for their data to be shared widely. Populations that do not have a strong trust relationship with the research enterprise, or who have historically been disenfranchised or harmed by research, may well demand such control. Limitations: The ACT Study population may not be representative of research participants more generally: they are 65 or older, are longstanding members of a health cooperative, have altruistic interests in research, and express strong trust in Group Health and the ACT Study investigators.

Next Steps

These findings are being prepared for journal publication. To determine how the results of this study compare with the views of other study populations, and whether participants’ views differ with respect to consent for prospective data collection, the research team has a grant in preparation to explore the views of participants enrolling in a newly established biobank.
Joseph Gibbons, MD; Cristina Ferrazzano Yaussy, MPH, CCRP; Jordan Hoile; Mr. Philip A. Cola, M.A.; Carol Fedor, RN, ND, CCRC

Topic: QA/QI

Problem/Issue Statement

Over the past decade, prospective monitoring of clinical research has been an ever increasing and valuable trend. Academic Medical Centers (AMC) have created programs and processes to monitor ongoing research and provide subsequent educational opportunities as a result of the monitoring1. Locally, a critical aspect of these activities has been the development of an interface between the Institutional Review Board (IRB) Office and the Office of Research Compliance and Education (ORC) at University Hospitals Case Medical Center (UHCMC). The purpose of this research was to identify the action items most encountered on monitoring visits, which could then be used to improve the quality of IRB administrative guidance and to provide information as an additional source of continuous quality improvement to the research practices at this institution. We hope to further understand the IRB operational and research quality improvement implications from a prospective protocol monitoring program in an AMC.

Description of Program/Research

Methods

In 2009, the UHCMC ORC monitored a total of 70 protocols. We conducted a retrospective review of the observations from these monitored protocols for both quantitative and qualitative measures (see Table 1). The monitoring process includes: protocol selection; investigator notification; monitoring preparation; pre-monitoring and pre-consent observation interviews; consent observation; monitoring; verification of Human Subjects Protections certification; grants and contracts review; conflict of interest; billing compliance; pharmacy services; clinical trials unit. Once all components are monitored, a final report is generated, reviewed with the ORC Manager and IRB Chair, prior to dissemination to the Investigator. Within these reports, the observations are categorized as outlined in Table 1; data collection and source documentation, grants and contracts, human subject protections, informed consent document, IRB documentation, potential non-compliance, protocol, regulatory, study personnel, and test article accountability. This systematic reporting method has allowed for a qualitative and quantitative review of the observations noted during the monitoring review, and included those needing immediate attention and items which were recommended to achieve the highest possible quality of responsible research.

Results

Category of Observation (Total/Percentage):
Data Collection & Source Documentation 155/28.5%
Grants and Contracts 41/7.6%
Human Subject Protections 44/8.1%
Informed Consent 12/25.1%
IRB documentation 5/0.9%
Potential Non-Compliance 25/4.6%
Protocol 36/6.6%
Regulatory 86/15.8%
Study Personnel 5/0.9%
Test article accountability 20/3.7%
Total observations- 543

Conclusions

The data indicate that there are significant overlaps, and thus opportunities, that exist between the IRB and ORC to continue to enhance the responsible conduct of research. In order to do this in a systematic and effective manner, it
is imperative that the IRB and ORC work toward continuous quality improvement in the following areas: informed consent documentation and processes; training of study personnel; research HIPAA; study conduct; and overall documentation.

**Next Steps**
The ORC and IRB must continue to routinely review the trends and strategies for specific approaches to better educate all members of the research community. This information can be used in creating new, useful educational programming and more suitable guidance programs to proactively support the research community. These observations will prove useful to other institutions by better equipping their research administrators with information as to specifically where research staffs typically encounter difficulty. Use of electronic systems will allow more efficient analysis of data which may be further interpreted and developed through education.

**Additional Information**

Incarcerated Individuals and HIV/AIDS Research: Incentives and Monetary Compensation for Research Participation
Gloria D. Eldridge, Ph.D.; Dr. Christiane Brems, Ph.D., ABPP; Staci Corey, M.S.; Mark E. Johnson, Ph.D.

Topic: Special Populations

Problem/Issue Statement

Although federal regulations have been developed to protect incarcerated people as research participants, these regulations and associated ethical guidelines are virtually silent on the issue of compensation for research participation by incarcerated people. The only exception to this silence is a focus on the importance of preserving autonomy to make voluntary and informed decisions to participate or not participate in research. However, given the environment in which these individuals are approached to participate, ensuring autonomy is not without considerable challenge or controversy. This is the first empirical study to investigate challenges and practices in the use of compensation for prisoners as research participants.

Description of Program/Research

Methods

A nationwide sample of 92 individuals with experience and/or knowledge in the conduct or oversight of HIV/AIDS research in correctional settings participated in a 60-90 minute, semi-structured phone interview. A purposeful sample was identified through consultants, literature reviews, internet searches, and snowball sampling. The sample included 30 researchers, 15 corrections administrators, 15 research ethicists, and 16 IRB members/chairs and 16 IRB prisoner representatives. Interviews were audio-recorded, transcribed and analyzed using NVIVO software for qualitative data analysis. This analysis focused on the issue of providing monetary compensation for incarcerated people participating in HIV/AIDS research.

Results

This study illustrated the interactions between direct benefits accruing from research participation, non-monetary incentives, and monetary compensation for research participation. Four main themes arose. First was the extreme variability across correctional institutions and IRBs in their approval of monetary compensation and other incentives for research participation. Second was the administrative burden implicit in providing compensation in a correctional environment. Third was finding balance between justice and autonomy. Research participants in non-correctional environments are routinely compensated; however, the deprived circumstances in which incarcerated people live render even modest monetary compensation potentially coercive. Fourth was the impact of non-monetary incentives for participation. In correctional environments, opportunities for a “break” in the daily routine or to interact with research staff are significant incentives for participation. Fifth was a concern that monetary payments remove the opportunity for incarcerated people to exercise altruism in their decision to participate in research.

Additional Information

This study is a first step towards understanding the interactions of direct benefits, non-monetary incentives, and monetary compensation for incarcerated individuals participating in HIV/AIDS research. Results from this study will be used to develop guidelines surrounding the use of monetary compensation and non-monetary incentives for participation in research among incarcerated individuals.
Incarcerated Populations: Recommendations for Conducting HIV/AIDS Research
Staci Corey, MS; Gloria D. Eldridge, PhD; Christiane Brems, PhD, ABPP; Mark E. Johnson, PhD

Topic: Special Populations

Problem/Issue Statement
Given the high rates of HIV/AIDS and related risk behaviors in individuals who pass through correctional settings, incarceration offers an opportune time for HIV/AIDS prevention and treatment research with this population. Unfortunately, various regulatory, ethical, policy, and structural challenges have limited the growth of HIV/AIDS research in correctional settings. This is the first empirical study to investigate specific recommendations for researchers in the conduct of HIV/AIDS research with incarcerated populations.

Description of Program/Research

Methods
Based on literature reviews and snowball sampling, a nationwide sample of 92 individuals with experience in the conduct or oversight of HIV-related research in correctional systems participated in a 60-90 minute key informant interview conducted by telephone. The sample included 30 researchers, 15 prison administrators, 15 research ethicists, 16 IRB members or chairs and 16 IRB prisoner representatives. Interviews were audio-recorded, transcribed and analyzed using NVivo software for qualitative data analysis. The current analysis focused on the question: “Within the context of HIV/AIDS research with incarcerated people, what are the three most important things you would tell someone embarking on this kind of work?”

Results
Several key themes emerged that were considered by most participants to be critical considerations when conducting HIV/AIDS research in correctional settings. First, participants stressed the importance of collaborating with all stakeholders involved in every stage of the research project, including correctional system staff members, participants, regulatory oversight bodies, and experts in the field. Second, it was emphasized that it is crucial that researchers be knowledgeable about the stakeholders with whom you are working, as well as the rules and regulations of the systems in which you are working. Third, participants underscored the vital importance of ensuring informed consent, respect for persons, and the principles of beneficence and justice.

Conclusions
This study is an important step towards understanding and addressing the challenges of conducting HIV/AIDS research in correctional settings and developing solutions to continue the growth of this type of research. More research is needed to further expand these areas of recommendations and to sample a wider range of respondents with experience in HIV/AIDS research with incarcerated populations. To gain a broader and deeper perspective on these issues, the next step in our research program is the launch of a quantitative survey based on these qualitative findings. This survey will be administered to a national sample of over 2,500 IRB members and HIV/AIDS researchers.
Informed Consent in High-Throughput Genomic Research: Views of Health Plan Members
Susan B. Trinidad; Stephanie M. Fullerton; Gail P. Jarvik; Eric B. Larson; Wylie Burke

Topic: Informed Consent

Problem/Issue Statement
As has been demonstrated by Arizona State University recent legal settlement with the Havasupai Tribe and the Texas case regarding the research use of newborn screening blood spots, genetic researchers can run into serious trouble if informed consent is handled inappropriately, or if researchers are perceived to have misled participants about how their samples could be used. Current federal policies strongly encourage data sharing within the research community through such tools as the database of Genotypes and Phenotypes (dbGaP), thereby increasing the potential for individual participants’ data to be used by others, for study purposes beyond what participants may believe they signed up for. This report addresses the following questions: What do potential research participants think about informed consent for research involving genomic information, data derived from electronic medical records, and broad data sharing? Under what circumstances would they want researchers to re-contact them to ask for additional permissions?

Description of Program/Research

Method
As part of a larger study of the beliefs, attitudes, and preferences of research participants and potential participants toward high-throughput genomic research, we conducted 6 focus groups with randomly selected members of a large, Seattle-area health maintenance organization. We held 2 separate sessions with members aged 18-34; 2 with members aged 35-50; and 2 with members older than 50. Each 2-hour session was co-facilitated by two members of the research team. Detailed field notes were written, and each session was audio recorded and transcribed. The study was approved by the Group Health Research Institute IRB, and written informed consent was obtained from all participants.

Results
A total of 45 participants (mean age = 32, 40% female, 87% white, 80% bachelor’s degree or higher) took part in these discussions. Participants placed high value on being told up front how their de-identified study information could be used, including the study purpose, possible future uses, whether data may be shared more broadly, with whom data may be shared, and how secondary data users may use the data. The majority of participants endorsed re-consent for changes in study purpose and data sharing beyond the scope of the original consent, articulating several different rationales for this position. Participants expressed a continuum of opinions with respect to the acceptability of broad consent, ranging from completely acceptable to completely unacceptable. A tiered approach to consent for specific issues including research purpose, data sharing, and return of individual results â€“ was favored by many participants.

Conclusions
Participants were interested in information and control with respect to the use of their data in research. Our findings suggest that broad consent, proposed by some experts as the optimal approach to biobank-based research, may be unacceptable to many potential participants. Further research is needed to investigate the role of biobank governance and bioinformatic approaches to operationalizing participant choice. Limitations: Participants are not a nationally representative sample in terms of race/ethnicity and educational level. Individuals unwilling to participate in research, or who hold strongly negative views with respect to genetic research, may have been less likely to take part in these focus groups. Next Steps: We are continuing to analyze the focus group data for additional insights about participants preferences, e.g., with respect to the return of research findings. This research team has a grant in preparation that would further explore participant perceptions and add parallel investigations of the views of IRBs, researchers, bioinformaticians, and others involved in planning and conducting such studies.
IRB chair perspectives on genomic incidental findings
Christian Simon; Sandra Daack-Hirsch, PhD; Janet Williams; Laura Shinkunas

Topic: IRB Operations

Problem/Issue Statement

Background Incidental findings (IFs) in research are findings unrelated to the aims of the research, but that may significantly affect the health and wellbeing of research subjects and their kin. Current directions in genomic sequencing are leading to major changes in the quantity and potential interpretability of IFs. Empirical data are needed to guide both national and local policy and best practices on the management of genomic IFs. Aims a 2-year, NIH-funded study is being conducted to explore the perspectives of biomedical IRB Chairs and other stakeholders on IFs in genomics research and clinical practice. The aim of this preliminary report is to identify early trends in IRB Chair perspectives on the challenges facing their human subjects protection programs with respect to genomic IFs.

Description of Program/Research

Methods
Semi-structured telephone interviews are being conducted with a sample of 40 biomedical IRB Chairs based at 40 discrete academic and nonacademic U.S. institutions active in genomics research. Eligible institutions and IRBs were identified through a review of 187 GWAS grant abstracts in NIH RePORTER and 417 GWAS publications archived in the National Human Genome Research Institute’s catalog of published GWAS. Data Analysis to date, 15 interviews have been completed and 7 have undergone preliminary analysis. Interview data are qualitative and quantitative, and include numerical data on IRB Chair demographics, IRB size and review volume, reported IF frequency and projected frequencies, and institutional context.

Results
When asked to identify the issues their IRBs currently or potentially face with respect to genomic IFs, IRB Chairs talked of the challenges associated with the interpretability of genomic IFs; the potential risks or harms posed by IFs with respect to individual research subjects and certain ethnic and cultural groups; how research subjects will be informed of genomic IFs; who will do the informing; what they will be told; and what will be needed by way of subject follow up. When asked to identify which issue would be most challenging for their IRB to contend with, IRB Chairs identified a variety of issues ranging from the potential to psychologically harm subjects with IF disclosures to the secondary analysis of genomic IFs in future research studies. No biomedical IRB Chairs have yet reported having a written policy or plan for managing genomic IFs.

Conclusion
Early indications are that IRB Chairs associate multiple ethical and organizational challenges with the occurrence, or potential for genomic IFs to occur, at their institutions. These results are preliminary and limited to the perspective of IRB Chairs. Additional data are needed to determine the scope and content of IRB Chair perspectives on the challenges of genomic incidental findings to IRB operations and human subjects protection.

Additional Information
It is anticipated that the final poster presentation will report on 15-25 interviews with IRB chairs.
IRB issues in nursing education
*Hunter Bellevue School of Nursing*
Dr. Joyce P. Griffin-Sobel; Dr. Pamela Y. Mahon

**Topic:** Ethics and Risk Assessment

**Problem/Issue Statement**

Nurse educators engaging in research on teaching/learning strategies with patients, health care agencies or nursing students are utilizing a variety of methodologies, data collection sites, and instruments. Innovative educational tools such as virtual reality, technology-enhanced learning, online education, simulation based learning and combinations of the above require rigorous evaluation. Nurse researchers must continue to develop the science of nursing education by determining the most effective teaching and learning strategies. However, Institutional Review Boards (IRB) are raising important questions to researchers about research ethics with newer pedagogical technologies. This study examined knowledge, skill and attitudes of nurse educators on IRB issues related to nursing specific pedagogical technologies.

**Description of Program/Research**

Nurse educators across the country were surveyed in an online format. Data collection is ongoing and to date 100 educators have responded, revealing much confusion about research ethics issues in online/internet research ethics, security problems with online commercial survey tools, privacy issues for student research, human subject issues specific to academic environments, and other areas that can lead to problems obtaining approval from an IRB.
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.

Description of Program/Research

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.
Medical errors—what does the Nigerian Patient want to know or be told?
Dr. Onochie Ike. Okoye, MBBS; Barrister Amaka Nkechinyelu. Ufodiama, LL B, BL; Mr. Solomon Ebuka Chibuzor, HND

Topic: Informed Consent

Problem/Issue Statement

Many physicians and even laymen are familiar with the laudable injunction to "first do no harm" which they have erroneously ascribed to Hippocrates, "the Father of Medicine". However, medical errors do occur, especially in a resource-constrained setting such as in Nigeria, and are likely to continue as long as mere mortals continue to practice medicine. Once these errors occur, what are the expectations of the average Nigerian patient? What does this patient want to know or be told? This presentation explores the key aspects of information disclosure with respect to how, what, when and why these patients wish to know about such medical errors.

Description of Program/Research

Methods
A self-administered 20-item questionnaire was distributed among willing consecutive patients attending the eye clinic of the University Of Nigeria Teaching Hospital over one week in January 2010. Results were collated and frequency counts/percentages were generated. Test of association for statistical significance was done using the chi-square test. Data analysis was done with the Epi-info version 6.

Results
The majority (78%) wished to be informed of any medical error, though with varying responses as to the level of disclosure required. Few (<20%) agreed that there may be situations where it may be better not to disclose a medical error to a patient. None had ever been told about a medical error by their attending caregiver.

Conclusions
There may be a need to devise a mechanism for encouraging and supporting disclosure of medical errors by Nigerian physicians, when they occur. A paradigm shift from the paternalistic model of doctor/patient relationship to that of mutual decision-making may be helpful in our society.
New Roles for Community Partners in Research - Developing Temporary Satellite Advocates for Research (TSARs)
Solomon Luckett, Jr.; Amy Prorock-Ernest; Rebecca Foco; Joseph P. Ornato; Cornelia Ramsey; Elizabeth B. Ripley

Topic: Ethics and Risk Assessment

Problem/Issue Statement

Virginia Commonwealth University has been partnering with the community in the past, and is continuing to explore new models and best practices for these partnerships. Emergency Medical Services (EMS) providers are participating in emergency research both as providers of interventions and as data collectors. One type of research in this setting is Exception from Informed Consent Research (EFIC). One of the new models of community engaged research is the development of Temporary Satellite Advocates for Research (TSARs) which occur when a community site is actively involved in helping to conduct the research. EMS providers as they conduct the EFIC trial are therefore TSARs. This study was designed to evaluate the attitudes, opinions, and practices of EMS providers (TSARs) in conducting emergency research in collaboration with the university.

Description of Program/Research

Methods
Twenty-seven in-context interviews were conducted at the Richmond Ambulance Authority facility. The interviews were tape recorded, transcribed verbatim and analyzed for themes utilizing NVivo®. Key themes are being identified and will be presented to the EMS providers in focus groups for validation during the summer of 2010. KEY FINDINGS Emerging themes to date, include attitudes and perceptions regarding research in general and EFIC in particular, the necessary training and preparation to equip the staff to conduct the research, concerns about communication, provider roles, data management especially patient information, the workload and workflow required for the research. An important finding was the key role of non-field staff (communication officers and administration) in the preparation and implementation of the study.

Conclusions
EMS providers and non-field staff have valuable insights, knowledge, and skills necessary to conduct emergency pre-hospital research. The input from these key partners must be sought at the earliest stages in planning and are an invaluable resource throughout the research process. TSARs can be developed and play key roles in research. EMS Providers and non-field staff are excited and interested in continuing their role as TSARs. FUTURE DIRECTIONS After the focus groups validate the findings, best practices regarding education, training, design, roles for EMS providers and non-field staff in designing, implementing and conducting emergency research will be developed. This study is supported by an NIH GRANT RC1NR011536-01
Nigerian Physicians' awareness of the Hippocratic oath, physicians' oath declaration, the code of medical ethics and the National code of health research ethics

Dr. Onochie Ike. Okoye, MBBS, FM COphth, FICS; Barrister Amaka Nkechinyelu. Ufodiama, LL B, BL; Mr. Solomon Ebuka. Chibuzor, HND; Mrs. Onyinye Nnennia. Okoye

Topic: Regulations and Guidelines

Problem/Issue Statement

The medical profession is being forced to face hard choices in patient care/ health research and to re-examine its own role in these endeavors, thereby causing it to look again at the nature of its own values. Despite the availability of regulatory codes, complaints against medical doctors bordering on unprofessional conduct continue to increase. Litigation addressing medical negligence, malpractice and lack of integrity continue to abound. This presentation determines the level of awareness of medical doctors in Nigeria of the contents of 4 of such regulatory codes or declarations.

Description of Program/Research

Methods

A 20-item self-administered questionnaire re-stating the key contents of these 4 codes or declarations was distributed among consenting interns or house officers employed at the university Of Nigeria teaching hospital, ituku-ozalla, Nigeria in January 2010. A simple Likert scale was adopted to measure level of agreement with each statement. Simple data analysis such as frequency counts, percentages, mean and mode was done using the Epi-info version 6.

Results

Majority (88%) agreed that medicine could still be practiced in Nigeria according to these guidelines. Few had heard of the National code of health research ethics. A smaller proportion of the respondents were shown to be familiar with the contents of the Hippocratic oath than with the Physicians' oath declaration.

Conclusion

The oath taking ceremony for graduating medical students should be made less of a perfunctory chore or ritual and more of a systematic continuous internalization of the required values. There is a strong need for formal ethics education for all medical graduates in Nigeria.
Parental Beliefs Regarding Research Integrity: A Pilot Study
Dr. Stephen J. Cico; Dr Eva Vogeley; Dr. William J. Doyle

Topic: Informed Consent

Problem/Issue Statement

Background: Human research involves the close interaction between researchers and participants within an environment of mutual “trust”. Objective: To explore the degree of trust assigned to medical research/researchers by unselected adults presenting with a child to the ED of a pediatric hospital.

Description of Program/Research

Methods
A questionnaire was used to collect information on demographics, knowledge of the Tuskegee Study, belief that government research is responsible for diseases, and beliefs regarding researcher motivations and honesty. We tested 2 hypotheses: 1) knowledge of the Tuskegee Study contributes to “mistrust in research, and 2) Blacks have an unfavorable view of medical researchers/research.

Results
395 questionnaires were complete for most questions. Black, female respondents were more likely to have heard of the Tuskegee Study and this was factually informed. 53% of the respondents who answered the question “Government funded research is responsible for which disease epidemic in the US” choose “none” and logistic regression identified sex (male>female) and having heard of the Tuskegee Study (heard>not heard) as predictors of that response. AIDS (26%), polio (13%) and anthrax (8%) were the most frequently listed diseases. Agreement with statements that reflected negatively on researchers was low, and most believed that researchers are honest and trustworthy. Older age, lower income and being female and non-white negatively skewed these attitudes and this was linked to purity of researcher motivation.

Conclusions
We reject our first hypothesis but accept the second and suggest that embedding the motivational trust of the physician/patient dyad within the researcher/subject dyad may redress biases in research attitudes. Future Applications: We hope to further explore the relationship between physicians and patients with regard to research involvement and to explore other barriers to participation which may exist, perceived or otherwise.
Practical Strategies and Advice for Managing Ethical Concerns in End-of-Life Research
Susan E. Hickman; Juliana Cartwright; Christine A. Nelson; Kathleen Knafl; Susan B. Bankowski

Topic: Special Populations

Problem/Issue Statement
A growing national interest in improving end-of-life care has increased the amount of research involving dying patients and their families. However, questions about how to best balance the pressing need for research with protecting participants trouble both investigators and institutional review boards (IRBs). Furthermore, ethical concerns were identified as a potential barrier to advancing end-of-life science at the 2004 NIH State of the Science Consensus Conference. This NIH-funded study describes ethical concerns and practical strategies for managing ethical challenges in the conduct of end-of-life research.

Description of Program/Research

Methods
A qualitative, exploratory case study design followed the development of end-of-life research from proposal generation through the review process. Inclusion criteria mirrored those used in the NIH State of the Science Report. Cases were identified through a search of active studies in the NIH RePORT database and an internet search of active research funded by private foundations and institutions. Data were collected from a purposive sample of 34 principal investigators who participated by phone in semi-structured interviews and provided document data regarding their experiences with the grant and IRB review processes. Interviews were recorded and transcribed with identifying information removed to protect confidentiality. Relevant document data were extracted and de-identified. Data were analyzed using exploratory qualitative case study methods.

Results
The most common ethical concerns about research with end-of-life populations were recruitment strategies, the burden of study procedures, and population vulnerability. Strategies to address these concerns included gathering data about the benefits of research participation, consulting with the IRB and with more experienced researchers, using non-threatening language in the consent and other materials, being flexible in data collection protocols to accommodate participant limitations, creating back-up plans in the event of crisis, partnering with clinicians to ensure prompt attention to symptom reports, and addressing the training and emotional needs of research staff. PIs advise IRBs to seek out expert consultants for end-of-life studies, work collaboratively with investigators, simplify the consent process, and be open to the benefits of research participation for dying patients and their families rather than assuming harm will occur.

Conclusion
Investigators use a variety of strategies to manage ethical issues in the conduct of end-of-life research. They advise IRBs to seek out expertise, enhance knowledge of the population, and work collaboratively with investigators. Future research will focus on gathering systematic data regarding the experiences of dying patients and their families with end-of-life research.
Reflections in medical ethics: the perspective of final year medical students in the University Of Nigeria, Enugu Campus
Dr. Onochie Ike. Okoye, MBSS, FMCOphth, FICS; Mr. Solomon Ebuka. Chibuzor, HND; Barrister Amaka Nkechinyelu. Ufodiama, LL B, BL; Mrs Onyinye Nennia.Okoye

Topic: Special Populations

Problem/Issue Statement
Most medical schools in Nigeria do not seem to have a formal, practicable ethics component of their curriculum. There are increasing reports of unethical conduct of medical students with patients, as well as their colleagues. The average Nigerian patient is gradually becoming more assertive of his fundamental rights. The study highlights the views of these medical students in relation to some issues in medical ethics, in order to obtain baseline information which may be applied in developing the ethics component of the medical school curriculum, and also in their future professional conduct.

Description of Program/Research

Methods
A 25-item self-administered questionnaire was distributed among a cross-section of final year medical students of the University Of Nigeria in January 2010. The respondents indicated if they or disagree with the issues raised, and the gradation of the responses was provided in a Likert scale ranging from 1-5. Data obtained were analyzed with Epi-info version 6.

Results
Majority of the students (98%) agreed that medical ethics should be taught formally as a course in the school, for which students should be evaluated on. Majority (75%) disagreed with the statement that patients should be informed of errors by medical personnel. Majority (>60%) disagreed with the statement that the patient's wishes must always be obeyed.

Conclusion
There is a need to identify pertinent, topical ethical issues in our environment which confront the average medical student and fresh medical graduate, with a view to providing him with the knowledge and skills required to handle such issues. Formalized instruction in medical ethics will be promoted in these schools.
Research Coordinators Perceptions Regarding Not-For-Profit (Local) Institutional Review Boards (IRB’s) Versus For-Profit Central Institutional Review Boards (CIRB’s)
Kathleen A. Seabolt, CIM

Topic: IRB Operations

Problem/Issue Statement

Background and Purpose: For years researchers have been grappling with issues related to the use of Local IRB's and Central IRB's. With the increase of multi-center studies, the argument for using Central IRB's is growing louder. On the other hand, local institutions are equally as vocal about not giving up their ability to monitor studies being done in their facilities. Research Question: What are the perceptions of research coordinators with regards to: 1. Financial conflicts with CIRB's since they are in business to perform reviews; 2. Availability of reviewers with relevant expertise for specialized studies; 3. The liability of Local IRB's relative to CIRB oversight; and 4. Other issues as identified in the literature.

Description of Program/Research

Methods
A researcher-designed survey was e-mailed to research coordinators to obtain their perceptions about Local and Central IRB's. The survey consisted of 10 questions. Responses are recorded on a semantic differential scale with two anchors, "strongly disagree" and "strongly agree". Data was analyzed using the Statistical Package for the Social Sciences (SPSS). Demographic data was analyzed using descriptive statistics. A Chi square analysis was performed to identify areas of importance using a significance level of p<.05. Results: Respondents fell into the following categories: 26% submitted solely to Local IRB's, 16% submitted solely to Central IRB's, and 58% submitted to both Local and Central IRB's. As expected, those research coordinators that used IRB's only had a more favorable perception of Local IRB's and those that only used Central IRB's had a more favorable perception of Central IRB's. Interestingly, those that submitted to both types of IRB's also tended to have a more favorable perception of Central IRB's. The results from this group were also the same when they were asked about the IRB's ability to find IRB members with more specialized knowledge and the quality of the review performed by both types of IRB's. Most telling was the prevailing opinion that Local IRB's should accept Central IRB reviews for multi-center studies. Conclusions: While the study was limited due to a low response rate (10%), it demonstrates that perceptions could be undermining the ability of the different IRB's to work together. It is obvious that more education regarding the use of each type of IRB is needed. Whether any middle ground is reach, it is important to remember that both types of IRB's are working to protect the rights of research subjects and to keep them safe.
Research Ethics in Hong Kong: Report on a Multidisciplinary Survey at University of Hong Kong
Sara R. Jordan, PhD

Topic: International

Problem/Issue Statement

While most universities in Hong Kong have human subjects research protection committees, these committees operate under conditions of relative uncertainty, implementing international standards and expectations in a setting where the form and substance of such committees may be misaligned with faculty knowledge, attitudes, and expectations. Further, few universities in Hong Kong are implementing a systematic training program to enhance understanding of RCR, leading to further knowledge deficits. At the University of Hong Kong, a pilot program to teach RCR to faculty and graduate students was launched in 2009, unfortunately before a baseline of knowledge and attitudes was assessed. However, a survey was initiated in May 2010 to gather more systematic evidence about RCR at University of Hong Kong and to generate data for use in attempts to improve the quality and content of RCR training programs. The question that spurred this survey and motivates this poster presentation is: What is the baseline level of knowledge and baseline attitude towards Responsible Conduct of Research amongst faculty members at University of Hong Kong?

Description of Program/Research

The data reported in this poster is derived from an online survey open to all University of Hong Kong (HKU) faculty members from April 26 to June 28, 2010. The survey was administered via surveymonkey.com and all faculty were initially contacted through the Personnel Office of HKU with the link. Follow up contacts via paper and via notices to heads of departments were sent at 1 month and 6 weeks respectively. The original sample size was 1846 faculty, inclusive of clinical assistant professors and faculty in affiliated units (e.g., Journalism and Media Studies Center). The survey was conducted anonymously and asked only closed ended questions to limit possibility of respondents disclosing their identity through open ended comments. Findings from the survey (on going at the time of abstract submission) will be presented in the poster. Preliminary findings suggest a lower level of knowledge about major documents and principles than expected, but a higher level of accommodation and positive attitude towards RCR than expected. Limitations to this study include online survey design, methods of respondent contact (initial online), and selection bias amongst respondents already briefed about RCR in other venues. However, the limitations of the survey are also illustrative for future studies to be conducted in all universities in Hong Kong in 2011.
Retention of information from written consent forms and reactions to research participation among university students

Rosemary Cogan; Brendan McDonald; Angela Eaton

Topic: Informed Consent

Problem/Issue Statement

Autonomy with respect to research participation is a basic ethical principle in research, part of the Belmont Report’s respect for persons. To decide about research participation, participants must have information about what participation will involve, often presented in a written consent form. In a series of studies, we are considering subjects’ understanding of consent forms as a function of characteristics of consent forms, experimenters, and subjects.

Description of Program/Research

Here we compare subjects’ retention of information from written consent forms and reactions to research participation as a function of four variations in the format of consent forms, as a function of the warmth of the experimenter, and as a function of the students’ critical thinking skills level. Method Two hundred and twenty eight students from introductory psychology classes participated in groups of one to six people randomly assigned to conditions. Students were given one of four consent forms written at the 7th grade Flesch-Kincaid reading level: standard formatting, friendly “you” formatting, reformatted with headings, or friendly “you” formatting with headings. The experimenter interacted with the students in either a “warm” or a “cool” manner. After consent was obtained, students were asked to complete a 10-item, multiple choice questionnaire containing questions about the consent forms they had just completed. Subjects were then asked to complete a demographic questionnaire and the Scale of Intellectual Development (SID), in counterbalanced order, and the Reactions to Research Participation Questionnaire, presented last. Results Students given “friendly” reformatted consent forms performed better on the consent form questionnaire than those given consent forms with other formats, F (1,197) = 7.11, p = .008. Experimenter warmth had no effect on retention of information from the consent forms. Groups differing in consent form formatting or experimenter warmth did not differ in Reactions to Research Participation. Students with higher critical thinking skill levels answered more questions about the consent form correctly, F (1,158) = 5.86, p = .02, reported fewer perceived drawbacks to research participation, F (1,158) = 4.05, p = .05), and tended to have more positive attitudes about research participation (RRPQ Total Score), F (1,158) = 3.71, p = .06. Conclusions Using consent forms written with a friendly “you” format and using headings may be helpful for written consent forms. Subject critical thinking skills are also important in information retention and reactions to research participation.
Risky Sexual Behaviors Among Young Urban Females in Post-Conflict Liberia – Ethical Implications

Mrs. Oretha S. Perry, BBA; Dr. Stephen B. Kennedy, MPH; Ms Ernree M. Bee, BA; Mrs. Pearl W. Fahnbulleh, MA; Mrs. Wede M. Nagbe, BSc; Mrs. Ernlee B. Barbu, BA; Mr. Jemee K. Tegli, BBA

Topic: Special Populations

Problem/Issue Statement

Young urban females are less knowledgeable and/or unaware about ethical issues that surrounds HIV/AIDS and therefore less likely to use condom. However, due to poverty in this setting, most of the young females are bread winners for their families so as a result they have multiple sexual partners. By addressing these pressing issues the can be a way forward by paying special attention to the problem that young women are faced with in research.

Description of Program/Research

Globally, ethics in HIV prevention intervention study have cultural and value system that thread together. Liberia, a country in the west of Sub-Saharan Africa, has not escaped the massive and terrible effect of HIV/AIDS epidemic especially among vulnerable populations like young females. Data regarding the HIV/AIDS risk behaviors of young Liberian females have been relatively unavailable. In the presentation, we characterized the HIV/AIDS risk behaviors of young urban Liberian females and propose intervention strategies to mitigate the spread of the virus among this population. Ethics is associated with the overall mainstreaming issues that surround HIV prevention studies. The study was a community-based randomized controlled trial (RCT) implemented in Monrovia, Liberia.

This study employed a community-based randomized controlled trial (RCT). Study participants were randomly assigned to either a behavioral-driven HIV/AIDS prevention (intervention) program or a general health (comparison) program. Informed consent documents were issued to female subjects prior to enrollment into the study; and beneficence and confidentiality were fundamental aspect of the study. Eight-module curricula were administered to participants over a four-week period at the start of the program, and followed-up surveys were administered at 3 months, 6 months and 12 months to determine the effectiveness of the HIV/AIDS program. There are prospects that after one year of program completion, young urban females would effectively be aware of their rights and privileges when enrolled in a health intervention program. They would know the ethical principles that are involved during the entire process. We believe such information can be applied else in the developing world where females are enrolled for research subjects.

Additional Information

Ethics is a vital component in health research studies. Subjects recruited in such studies must be given a clear and concise understanding of their rights and privileges during the timeframe of the study. Young urban Liberian females are at risk for HIV/AIDS and at such they were given information about ethical issued prior to their enrollment. Strikingly, they are less likely to use condoms primarily due to the lack of knowledge in the usage of condom as a protective tool in HIV prevention, more likely to have multiple sexual partners, and less likely to be knowledgeable about HIV/AIDS. Additionally, gender inequalities and socio-economic disparities are major contributing factors. Cultural implications which place males as the dominant partners give females little or no choice in suggesting condom use as a mean of HIV/AIDS prevention. We conclude that the findings from the study will potentially contribute to the research and policy gaps associated with ethics in health research in Liberia. The risky sexual behavior among young urban females in post-conflict Liberia is a good example of what occurs during the implementation of such studies. Acknowledgement This study is funded by a grant [RO1 HD 045133] from the National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) in Bethesda, Maryland, USA.
The current state of bioethics in medical education in Japan - Analytical review of the syllabus of 65 medical schools in Japan -

Masayuki Yoshida, MD, PhD; Naoko Nii, RN, BN; Yuka Ozasa, RN, PhD; Masumi Ai, MD, PhD

Topic: International

Problem/Issue Statement

Since 2007, the importance and necessity of the education on bioethical matters have been included in the minimum requirements for medical school education program in Japan due to increased complexity of caring for patients and the development of new technologies including cloning and embryonic stem cells. Research question: Our aim of this study was to overview the current state of bioethics in medical education in medical schools in Japan, to seriously consider a better program for medical professionals in Japan.

Description of Program/Research

Methods
We surveyed the syllabuses for the school year 2008 of 65 medical schools in Japan (81% of all), and counted the school hours for bioethics in each grade of the medical schools (first-6th).

Results
During the 6 years of a whole course of Japanese medical school, the mean (SD) school hours for bioethics were 21.5 (17.3) hours. About 80% of the school hours on ethics were during the first and the second grades, and very few were during the 5th and the 6th. To explore the courses in detail, we categorized bioethics classes in three groups 1) medical ethics or ethics related medical practice, 2) research ethics, and 3) other ethical issues including end-of-life decision making. The number of school hours for medical ethics were as high as that of other ethical issues. All medical schools we surveyed opened these classes. On the contrary, 25% of medical schools did not provide any class for research ethics, and only 4 schools provided more than one class during the 6 years.

Conclusion
In Japan, medical schools provide classes on bioethics in their earlier grades such as 1st or 2nd year. Very few classes are available to the senior students such as 5th or 6 year students. Further, no medical schools can provide ample hours for research ethics. Our data documented for the first time that there is a substantial variation in the quantity and quality of bioethics curriculum in Japan. Future directions: We need to create the effective teaching programs in bioethics for medical students in Japan which will help to cultivate human supply for teaching faculty of this field.
Understanding the Relationship between Community-Based Processes for Research Ethics Review and Institution-based IRBs
Nancy Shore; Sarena D. Seifer; Elaine Drew

Problem/Issue Statement
A number of communities and community-institutional partnerships have established research ethics review processes. Our study sought to systematically describe community-based processes for research ethics review in the United States to gain insight into how ethics review of community-engaged research (CEnR) can be enhanced. Such understanding is essential given the increasing rate of CEnR and the growing body of literature that indicates how institution-based IRBs are not always able to provide a thorough and relevant ethical assessment of such research. Our poster presentation focuses upon how these community-based processes interface with institution-based IRBs, which includes questions pertaining to communication patterns and overall relationship considerations.

Description of Program/Research

Methods
We conducted an online survey of US-based community groups and community-institutional partnerships involved in research. We constructed a survey sample of 1,055 groups/partnerships by reviewing bibliographic, conference, and funding databases; contacting relevant organizations and listservs; and Internet searching. Key contacts were emailed study invitations. We performed descriptive statistical analyses using SAS version 9.1, and thematic content analysis of responses to open-ended questions.

Results
Out of the 200 completed surveys, we identified 109 ethics review processes that mainly function through community-institutional partnerships, community-based organizations, community health centers and tribes. These processes primarily formed to ensure the involved communities are engaged in and directly benefit from research, and are protected from research harms. Over 50% of the respondents indicated that all proposals assessed through their review process are also reviewed by an institution-based IRB. Primary reasons for involving an institution-based IRB included proposed research includes an institution-based partner (82%) and funders require it (58%). Forty-three percent of the respondents reported that their communication with the involved institution-based IRB varies, while 31% reported no communication. Twenty-three percent of the respondents reported that their relationship with the involved institution-based IRB was extremely positive, with an additional 30% reporting a somewhat positive relationship. Thirty-three percent characterized their relationship as neither positive nor negative. Our poster will highlight these and other findings.

Conclusions
Based upon study findings, we will present a set of recommendations aimed at enhancing the interface between community-based review processes and institution-based IRBs.

Limitations
With no readily available database of community groups/partnerships involved in research, our constructed study sample is not complete and may not be representative of all possible study participants. To increase the likelihood of reaching all invitees, we sent follow-up reminders and called a random sample of non-responders. Additionally we created a non-responder survey to compare the survey responders with the non-responders.

Next Steps
Subsequent study phases involve forming a collaborative research network with interested survey respondents and conducting in-depth case studies of selected community-based research ethics review processes.
Use of Data Collected Out of Compliance with Regulations for the Protection of Human Subjects
George Gasparis; Ms. Jessica Randall; Ms. Heather Butts; Marilyn Morris, MD

Topic: Ethics and Risk Assessment

Problem/Issue Statement

There is a lack of guidelines and national consensus on whether investigators should be allowed to use data collected out of compliance with the federal regulations for the protection of human subjects for publication or even to serve as a basis for future studies. There are ethical as well as practical considerations affecting determinations permitting the use of such data. The pros and cons of such use were articulated in a panel in the 2008 annual PRIM&R conference referenced as “The Great Debate”. While the FDA will consider all data collected under an IND or IDE application to fulfill its public health responsibilities, OHRP does not hold a position on use of such data. Instead, OHRP’s position is that, in general, the sponsor, institution, IRB, and investigator should determine whether data collected out of compliance should be used for publication purposes.

Description of Program/Research

This study involves semi-structured interviews with IRB Directors, IRB Chairs, Research Integrity Officers and others who may be involved at academic institutions with determinations as to whether and when data collected out of compliance may be used. The study surveys leading institutions in the United States based on NIH funding. The objective of the study is to determine the prevalence and content of written policies governing use of such data, and to describe the range of approaches institutions take regarding its use. The following specific types of noncompliance are assessed: 1) lack of IRB approval for both minimal risk and greater than minimal risk studies; 2) enrollment of subjects without legally effective informed consent; and 3) conducting greater than minimal risk procedures during a lapse in IRB approval. In effort to obtain a clear understanding of how institutions make such determinations, interviewees are asked how their institution generally has opined in the past year with regards to use of data for a specific example of each type of noncompliance. Preliminary data show that written procedures are not common; furthermore, there is a lack of clarity as to when use of data will be permitted.

Additional Information

Significance and Next Steps This pilot study will serve as a basis for larger studies in the future. Empirical data are necessary to gain a better understanding of the relevant ethical and administrative considerations on the issue that may eventually lead to a consensus position or guidance on the topic that would be a resource for IRBs and institutions.