Scientific Poster Abstracts from the 2007 HRPP Conference: Human Research Protection Programs in an Evolving Research Landscape

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## Abstract

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3R’s of reb/IRB membership – recruitment, retention and recognition
Author: Rachel S Rosenberg Zan

Background:
Maintaining a properly constituted, well-educated, and content Research Ethics Board (REB) or Institutional Review Board (IRB) is an important objective of every research institution that conducts human subjects research in compliance with federal regulations or guidelines. While the volume and complexity of work required of REBs/IRBs continues to increase, so does the challenge for REB/IRB administrators and chairs to maintain boards that can function at an optimal level, typically with extremely limited resources. The three major concerns of maintaining a healthy REB/IRB are: 1. Recruiting new members; 2. Retaining current members for the duration of their term; and 3. Recognizing members for their commitment to their work and to the research enterprise. Through informal conversations with REB/IRB administrators, chairs and members, these concerns seem to resonate throughout the research protections system. However, no concrete data exist to quantify the issues, and moreover, to describe ways in which institutions are developing creative strategies to solve them.

Research Question/Hypothesis:
The purpose of this study was to evaluate the issues faced by Canadian REBs with respect to recruiting, retaining and recognizing REB members. The objectives were to determine current trends and practices in the 3 R’s, and to understand what resources, from the perspective of REB administrators and members, may be required to resolve these issues adequately.

Methods:
After receiving ethics approval, an email was sent through the National Council on Human Ethics in Research (NCEHR) and the Canadian Association of Research Ethics Boards (CAREB) listservs to REB administrators, chairs and members inviting them to participate in an anonymous internet survey. This survey contained multiple-choice and open-ended questions on REB workload and composition, recruitment, retention and recognition of REB members, and educational opportunities.

Results:
85 REB administrators, chairs and members responded to the survey, with an approximately equal number of respondents in each category, representing medical and non-medical universities, teaching and community hospitals and independent REBs. The majority of participants indicated their institution had one REB responsible for reviewing heavy workloads of protocols spanning the full spectrum of research disciplines. Recruitment is typically done through word of mouth and takes time. The majority of respondents indicated that recruitment of new members is of concern. Retention was less so, with respondents indicating that a significant percentage of members meet or exceed their term limits. Recognition mechanisms for members and chairs include stipends/honoraria, course release, educational opportunities, receptions and token gifts. There was a large discrepancy in the resources available to institutions to recognize their members and the majority of respondents expressed that recognition of REB members and the research ethics system as a whole is of great concern.

Conclusions:
REB administrators, chairs and members in Canada are concerned with REB member recruitment and recognition, but are less concerned with member retention. Inconsistencies exist across the country with respect to the availability of tools to compensate and/or recognize REB members. Overall, there is a perception of a lack of resources to maintain optimal REB health across Canadian institutions. We hope to extend this study to a larger number of REBs and IRBs to collect further data, and determine whether there are differences in the Canadian versus American research protections system.
A Survey-based Study on the Perceptions of childhood assent among American and Non-American Researchers
Authors: Julian D. Rose (High School Senior) and Carlos D Rose MD, CIP

Background:
New drug development/approval now involves unprecedented international collaboration. In the US, the FDA accepts data gathered overseas and exercises auditing power on non-US sites. EMEA (EU) and Latin American agencies follow similar approval process. In pediatrics international collaboration is of utmost importance because recruiting children for clinical trials is hard and need for advancement urgent. Assent, the process whereby a minor agrees to participate, is intended to respect child’s autonomy and is mandated by law. The unknown aspects of assent include: 1-Conviction among researchers of assent’s importance 2-Perceived necessity by pediatric participants and 3-Degree of understanding of assent regulations among US and non-US researchers.

Research Question/Hypothesis:
We hypothesized that the majority of responding investigators will assume that children have a good level of understanding of the assent forms, that they will support and will have knowledge of the assent process.

Methods:
This IRB-approved survey based research involves an 18-question questionnaire consisting of four domains: 1- Demographic domain (questions 1-6); 2-Researcher prospective on assent (questions 7-14); 3-Researcher’s view of pediatric participant’s views on assent (questions 7-14); 4-Case studies to assess assent knowledge (questions 15-18)

Results:
Sample: Out of 500 questionnaires distributed there were 108 respondents (21.6%). 50 were females and 58 males. Ages ranged from 29 to 69 years and years since graduation from 3 to 43. Respondent’s self-defined race/ethnicity was: 78.5% Caucasian, 10.3% Hispanic, 9.3% Asian, and 1.9% African. Of 106 respondents providing highest degree, 3.8% were Masters, 74.0% MDs, 21.2% PhD and 1.0 % had PharmD. 57.4% of respondents were US nationals, and 42.6% either European or Latin Americans. Databases were obtained through Nemours Research Department, Pediatric Rheumatology Collaborative Study Group (US), PRES (Pediatric Rheumatology European Society) and PANLAR-Pediatrics (Pan-American Liege of Associations of Rheumatology (Latin America). Anonymous questionnaires were returned electronically to a third party who stripped email addresses and filed responses according to geographic origin. Perceptions: For the analysis from the 1-5 weighted responses, answers 1-2 were rendered as negative and 4-5 positive perceptions. 87% believed or strongly believed that child assent is necessary, while 67% believed or strongly believed that in certain conditions assent may be waivered. While only 60% believed or strongly believed that children find assent to be necessary, 79% believed or strongly believed that the autonomy with which children assent is limited. Also, 56% perceived that children do not understand what they are agreeing to participate in, 78% believed that children rarely or never ask questions about the risks of the research studies and 60% expect that children will not understand the rights embedded in the assent. Chi-square analysis was applied for the perceptual responses. Categories: MD/ Non-MD; Female/Male; Caucasian/Non-Caucasian and US/Non-US. There were no significant differences between the perception patterns for: Necessity of assent, waiver rules, children perception of need, children understanding, children inquiry and children understanding of rights. US respondents perceived less autonomy among children than their non-US counterparts (p<.025). Cognition: of the three knowledge testing case scenarios there were 298 responses ( 99, 102, and 97). Only 113 out of these 298 responses were correct (37.9%). Case 1: 63/99 (63.6%); case 2: 21/102 (20.6%); case 3: 29/97 (29.9%). Further analysis showed a significantly higher
rate of understanding among US nationals compared to non-US nationals. Overall, 83 out of 178 US responses were correct (46.6%), and 30 out of 119 non-US responses were correct (25.2%). This difference was highly significant with \( p=0.001 \) while MDs (43.6 correct) V.S. non-MD (36.6%) were non-significant. When comparisons were established between the entire group’s rate of correct responses and the subset of respondents reporting familiarity with US regulations, there was no significant difference. More notably, when we focused on the “knowledgeable group” (29 respondents self-defined as very familiar with the US regulations) alone, their rate of response was not significantly different either.

Limitations: 1-Study focused on investigators’ perceptions rather than assessment of perceptions and knowledge of pediatric participants directly; 2-Certain racial minorities were underrepresented in the sample.

Conclusions:
108/ 500 individuals from the US, Latin America, and Europe who conduct pediatric research/care responded. Our data suggests that this community is somewhat skeptical of the assent process while feeling assent should occur. Knowledge of assent regulations was poor among all respondents including those self-defined as familiar with regulations. Non-US researchers performed significantly worse. This data strongly argues in favor of the need for a thorough and comprehensive worldwide educational effort among the research community if the assent process is to improve as the same community perceives as necessary.

Future steps:
1-Expand target population to other pediatric specialties; 2-Involve pediatric participants by direct interview using qualitative research approach.
Additional Yet-to-be-defined Research Study Attached to a Clinical Trial Should Use Additional Informed Consent Document
Authors: Yen-Hong Kuo, Sc.M., M.S.; T. Patrick Hill, Ph.D.; Nasim Ahmed, M.D.

Background:
In order to extend the contribution from study participants in a clinical trial, researchers integrate the consents for additional yet-to-be-defined research studies into the main consent document. These additional research studies might include collecting blood and tissue samples for future research or research about other health problems. However, based on our recent review experiences, these extra consents resulted in confusion in the reviewers’ understanding of the main study. This raised a concern that the extra consents might jeopardize the participant’s decision making on participating in a clinical trial.

Research Question/Hypothesis:
The purpose of this study is to understand how local Institutional Review Boards (IRBs) handle the informed consent document of a multi-center clinical trail in which consents for the collection of blood/tissue samples for future studies are included.

Methods:
IRB approved informed consent documents from multi-center clinical trials were identified from the Internet in August 2007. The organization of consent information was assessed. When the extra consents are presented before the main consent signature area, it is considered as integrated.

Results:
Informed consent documents from three multi-center breast cancer clinical trials were chosen for this study. Four web sites were identified where the IRB approved informed consent documents were posted for public access. Eleven informed consent documents were reviewed and compared (2 studies were available from all 4 sites; 1 study was available from 3 sites). The number of pages in the informed consent document ranged from 10 to 20 pages. The number of pages and proportion of the extra consents ranged from 1.5 to 6 pages, and 15% to 30% of the whole document, respectively. Overall, four documents have the extra consents which are integrated within the main consent (36%). No specific layout was used to show the nature of extra consents. Two IRBs (50%) approved the integrated consent document: one IRB had all extra consents integrated; one IRB had mixed decision on the organization of extra consents (2 documents have the integrated extra consents; 1 document has the extra consent after the main consent’s signature area).

Conclusions:
A high percentage of informed consent document integrates the extra consent for extra study. IRB should request that researchers use additional informed consent document for additional research study to protect the integrity of the participant’s consent. Limitations: The number of web site which posted the IRB approved informed consent document is very limited. Therefore, the sample size is small. However, this study includes all the consent documents available from the Internet. The included web sites already represent our concern.

Next Steps:
The Policies and Procedures of IRBs which approved the included informed consent documents will be reviewed, if they are available on their web site. Recommendations for separate consents for the additional studies will be proposed.
Attitude of Biomedical Researchers in West Africa to Ethical Review of International Collaborative Research

Authors: Randina Clement A, Adebamowo, MD, FWACS, FACS, DSc; Temidayo O. Ogundiran, MD, MHSc; Efua Irene Amenyah; Jumoke Olanisebe

Background
International collaborative research is necessary in order to tackle modern health challenges posed by persisting health disparities, new and re-emerging health problems and support the attainment of health by populations in low resource environments. These research involve collaboration between biomedical researchers in developed and developing countries, however little is known about the attitude of biomedical researchers to the health research ethics issues posed by these developments. We evaluated the attitude of West African biomedical researchers to health research ethics and present some of their responses to questions related to review of international collaborative research conducted in Africa.

Research Question/Hypothesis
Who do biomedical researchers in West Africa think should provide ethical review of protocol in international collaborative research? Method: We conducted a cross sectional survey of biomedical researchers in 3 West African countries – Nigeria, Togo and Senegal – in 2005 and 2006. We asked questions about their attitude to ethical review of international collaborative research, common concerns raised by local and by international ethics committee within the context of these types of research and their experience of international collaborative research.

Findings
There were 345 respondents, 55% (188/345) from Nigeria, 27% (93/345) from Togo, 8% (28/345) from Senegal while the remaining 10% (36/345) did not indicate their country of practice. Most 61% (211/345) of the respondents work in tertiary or teaching hospitals or colleges of medicine, 15% (51/345) work in general hospitals or secondary health care centers, 4% (14/345) are based in research institutes, 2% (7/345) work in nongovernmental organizations, 1% (3/345) are in administrative aspects of research, while 15% (52/345) listed other places of work. Some 2% (7/345) did not indicate their place of work. About 17% (57/345) if the respondents indicated that they work in the surgical specialties (including dentistry, ophthalmology, ear, nose and throat surgery), 16% were in internal medicine specialties, 13% (44/345) work in obstetrics and gynecology, 10% (36/345) work in medical imaging, 5% (18/345) work in public health, 5% (17/345) work in pediatrics, 27% (92/345) work in different basic and clinical sciences or a combination of these while 8% (27/345) did not indicate their specialty.  Most, 27% (94/345) of the respondents believe that in international collaborative research, local ethics review alone is sufficient, 7% (24/345) think that review by the ethics committee of the international collaborator is sufficient, 25% (87/345) think both local and international collaborating institutions should review the research, 11% (39/345) think that third party ethics review is preferable, 2% (8/345) preferred both local and third party ethics review, 0.3% (1/345) wanted third party and international collaborating institution review, while 5% (18/345) preferred local, international and third party review. Some 21% (74/345) had no opinion about who should review research.

Conclusion
This study suggests that even where research is reviewed by ethics committee of the international collaborating institution or a third party, majority of biomedical researchers surveyed wants the local institutional ethics committee to play a role in review of international collaborative research.
College Students Opinions on the Use of Internet Social Networks for Research

Authors: Peter Vasilenko PhD, Nora Rifon PhD, PK Pathak PhD, Kristen Burt BS BA, John Kosciulek, PhD, Joseph Arvai PhD and Natalie Olinghouse

Background:
Online social networks are virtually universally used by college students. Because of the widespread use and diversity of information posted, investigators see these postings as gold mines of research data. This new area of technology and research has raised numerous issues and debates of the public nature of the postings, expectation of privacy, and permission, notification and consent issues. This project provides a preliminary analysis of data from college students.

Research Question:
The objective of this study was to survey college students to obtain their opinions on the use of online social networks for research.

Methods:
Online surveys were completed by 406 college students in two classes. For each question subjects were asked to determine if they strongly agreed, agreed, were neutral, disagreed, or strongly disagreed with a given statement. For simplification of this preliminary analysis agreed = strongly agreed + agreed and disagreed = disagreed + strongly disagreed.

Results:
When asked if online social network materials are public information that can be used for research without notification or consent, 58.5% agreed, 24.6% disagreed and 17% were neutral. However, if the material was restricted (e.g. friends only) 73.4% disagreed that the material is public and can be used without consent or notification. Only 29.4% of students had no problems with their information being used without their permission and 67.4% of students agreed that researchers should obtain permission from website owners and post that the material is being used for research. The majority of students (65.2%) felt that researchers should obtain individual consent before using materials. Using materials for research without consent or notification was thought to be an invasion of privacy by 65.6% of students. Of students, 66.9% felt that people would give permission to use their materials if asked, and 50.2% said they would give consent for their own material. Seventy-two % of students felt that people would alter what they post if they knew their information was being used for research, and 59.1% said they would alter their own material in that situation. Most students (57.5%; adults) recognized that they are giving up their right to privacy by posting information, but 23.5% disagreed. However, if it is minors posting, only 21.7% of students said the minors recognized that they are giving up their right of privacy and 52.4% disagreed. Nearly half (48.4%) of students felt that no one should have an expectation of privacy by posting information on social networks, while 27.7% disagreed. Only 18.4% of students felt that the knowledge gained from research is more important than the individual’s right to privacy, and 55.2% disagreed. Of all students only 26.8% thought that the use of materials without consent or notification did not present any ethical issues, 48.6% said it did raise ethical issues, and 24.6% were neutral.

Conclusions:
These data show that college students are clearly torn, and perhaps unaware of these issues and their rights and expectations. They recognize that social network postings are public, yet most have an expectation of privacy, especially if they restrict their own postings. Most believe website permission, notification of research and even individual consent is appropriate. Most students believe that they or others would change what they post online if they knew it was being used for research, which presents a quandary concerning the scientific integrity of such research. Internet research presents new opportunities as well as new ethical dilemmas for IRBs and investigators. This project is just a preliminary
glance at student opinions, which need to be further analyzed and expanded. In addition, we need to survey the opinions from IRB members and staff, researchers, and parents to get a complete idea of the diversity of opinions, the ethical issues, and potential solutions and directions for IRB considerations and actions.
Communicating the Results of Clinical Research to Participants: A Systematic Review
Authors: David I. Shalowitz AB, Franklin G. Miller PhD

Background:
Debate over investigators’ responsibility to communicate the results of clinical research concerns several empirical issues. However, the relevant data have not been systematically reviewed.

Research Question/Hypothesis:
We reviewed available data about the impact of communicating research results on investigators and study participants, as well as available data on current attitudes of participants and investigators regarding the communication of research results.

Methods:
PubMed, Medline and Cochrane Library databases, as well as manuscript references, were searched for studies published in English between 1950 and 2007. Selected for analysis were studies providing qualitative or quantitative data on communication of research results with respect to 1) research participants’ preferences, 2) investigators’ attitudes and practices, 3) the psychological or behavioral impact on participants, 4) costs of implementation or 5) the effect on participants’ perceptions of research or investigators. 22 manuscripts were identified based on these criteria. 8 studies were analyzed of 22 identified by the database search; 14 additional studies were analyzed after being identified through manuscript references.

Results:
A median of 90% of participants (range 71-100%) want to know the conclusions of studies in which they participated. A median of 69% of investigators (range 33-79%) support the communication of study conclusions, but communicate them in less than onehalf of cases. Available data suggest that undue anxiety and false reassurance are not major barriers to communication of research results. No data were found on costs of communication strategies or the effect of communicating results on perceptions of research as a whole.

Conclusions:
Available data strongly support the communication of study results to participants. Future research should focus on attitudes and impact specific to communicating data relevant to individual participants as well as comparatively assess methods of communication with respect to cost and effect on participants' view of research.
Differences in Perception Toward Potential Recruiting Materials as Related to Age, Education and Occupation
Authors: Jere M. Boyer, PhD; Donna Waechter, PhD; Rebecca Garner; Melissa Terwilliger; Namrata Dhillon

Background:
This is a three year on-going IRB approved research study that has examined various aspects of recruitment of subjects into research studies. Two years ago data was presented at PRIM&R showing several general differences in the interpretation of potential recruitment photographs that warranted further study (Waechter, D., Rice, M., Schlegel, E., et al.). Last year a study was presented elsewhere that indicated marked differences in gender when viewing research materials (Waechter, D., Boyer, J., Garner, R., et al.). The current study has examined the variables of age, education and occupation as related to potential recruits and recruiting materials.

Research Question/Hypothesis:
There are no differences in perception of recruiting materials when viewed by persons of differing age, education or occupations.

Methods:
A total of 185 persons (males accounted for 31.4% and 68.6% were females) were interviewed, using a standard script, at a large teaching hospital in both inpatient and outpatient settings. Subjects were consented, demographic data was obtained and subjects were shown ten pictures depicting a patient and a caregiver in various situations similar to those which are commonly used in research recruitment materials. Subjects were asked a series of questions regarding their perceptions of each of the ten photos. Some questions were open-ended and were analyzed via accepted qualitative procedures. Other questions yielded quantitative data that was entered into SPSS 15.0 for statistical analyses.

Results:
Educational Level: Forty eight percent of respondents had attended or completed high school and one individual had a grade education. Five percent had attended vocational school and the remainder (46%) had received higher education. All educational levels agreed that a photo of a subject undergoing a stress test would not encourage them to enter a research study. Interestingly, only those with graduate degrees felt that a picture of an elderly female undergoing physical therapy was least inviting. This was apparently due to this group’s common perception of patient discomfort. Education levels also impacted data about pictures that might be effective in recruiting. All except those receiving a vocational education thought that a picture of a subject receiving her medication and looking very interested in the process would encourage research participation. Those with a vocational education preferred a photo that showed a caregiver being helpful to the patient.

Age Groups: Participants were divided into four age groups: <35; 35 to 50; 51 to 65; >65. All age groups responded negatively to the picture of an elderly lady undergoing physical therapy (as did those with graduate degrees, above). However, only the youngest group did not like the photo of a physician who is counseling a patient. All age groups preferred the picture of a subject receiving her medications and looking very interested in the process. However, the 35 to 50 age group preferred the picture of a young health care professional assisting a patient in a wheelchair equally as well. This photo was not as well received by the other age groups.

Occupations: This group was fairly evenly distributed among laborers, blue collar workers, professionals, and retired/unemployed persons. There were minimal differences as to preferences for the recruiting materials based on occupation.

Conclusions:
Additional in-depth analyses are in progress. However, it is clear that subjects in this study were candid in identifying reasons for feeling that a particular photo would either help or hinder recruitment. Results from our previous studies, in addition to the present study, suggest that potential subjects do not like posed pictures. (The physician counseling the patient is an example.) Photos should depict individuals who appear to be happy and attentive. The quality of the photos is important, as is professional attire. It is hoped that results from the present and previous studies will assist researchers to produce recruiting materials that are inviting to potential research subjects, while keeping within ethical and good clinical practice guidelines. A limitation of this study is that our population is not as diverse as we would have liked, but does reflect the general population of the area. The authors plan continued analyses of available data.

References: