

September 29, 2008

VIA FEDERAL EXPRESS

Michael A. Carome, M.D.
Captain, U.S. Public Health Service
Office of Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Dr. Carome:

I am pleased to submit this response on behalf of Yale University to the Office of Human Research Protections' (OHRP, the Office) request for information and comments regarding human subjects protection training and education programs. (73 FR 37460) My Yale colleagues and I appreciate the opportunity to share our views on this important matter.

We understand that, based on OHRP's experience in compliance activities and on the advice of multiple advisory and regulatory bodies, OHRP believes that a number of individuals involved in the conduct and/or review of human subjects research have gaps in their knowledge about human subjects protections and suggests that these gaps may be symptomatic of inadequacies in institutional education and training programs. Accordingly, OHRP is seeking comment regarding the advisability of issuing additional OHRP guidance or seeking additional Health and Human Services regulation pertaining to such training and education programs.

We believe that research institutions have an obligation to protect human subjects participating in research, and, more specifically, we agree with OHRP that education and training programs are critical to institutions' success in meeting that obligation. That said, we feel there is an insufficient body of evidenced-based studies that 1) document the relation of deficiencies in specific features of education and training programs to instances of non-compliance; and 2) illuminate those educational measures that would be most effective in preventing non-compliance and improving human subjects protections. Accordingly, we feel that regulation regarding education and training would be premature and, in fact, could consume agency and institutional resources that could be more effectively deployed to other human subjects protections activities. Moreover, we urge that OHRP supplement and support any guidance on this matter with studies to measure the impact of educational and training programs on the effectiveness of human subjects protections programs and thereby assist institutions in identifying areas of vulnerability and opportunities for real improvement.

Yale University's Implementation of OHRP Training Recommendations

Yale University maintains a human subjects research education and training program that, as recommended in the terms of the Federalwide Assurance, includes all personnel who are involved in the conduct, review, and oversight of human subjects research, e.g., the Signatory Official; the Human Protections Administrator; Institutional Review Board (IRB) chairs, members, and staff; principal investigators; and research personnel named on research protocols (Question 1a). In accordance with this program, these personnel are required to complete basic training in human subjects protections by taking an on-line or face-to-face course in human subjects research protections provided by the University, taking courses provided by the National Institutes of Health (NIH) or the Collaborative Institutional Training Initiative (CITI), or by completing training that is deemed equivalent to that provided by the University, NIH, or CITI.

In addition to basic training, Yale provides additional orientation for new IRB members and regular educational updates for all IRB members during IRB meetings. A robust calendar of additional formal and informal educational offerings relating to ethical, regulatory, and administrative issues in the conduct of human subjects research is available to the entire Yale community and publicized through a number of venues including the Yale Interdisciplinary Bioethics Center.

Yale notifies the community of training requirements in human subjects protections and a number of other areas (e.g., conflict of interest, biosafety, sexual harassment, information security) and tracks compliance with these requirements through Yale-developed software, the Training Management System (TMS). Every faculty and staff member is asked to complete annually a TMS assessment profile that determines, based upon assessment responses as well as employment-related information, the types and frequency of required training. TMS also provides access to on-line courses and to registration for face-to-face training; issues certificates of completion; and maintains an on-line database of completed training, which can be accessed by faculty, staff, supervisors, and directors of compliance units.

Components of an Effective Education and Training Program

OHRP has asked institutions to comment on features of education and training programs that might be addressed in guidance or regulation. We believe that many of these features add value to an education and training program including:

- Inclusion of individuals involved in the conduct, review, and oversight of human subjects research (Question 2);
- Creation of a consistent level of basic, minimum training, meaningful for all participants in human subjects research, e.g., core ethical principles (Question 3a and Question 5);
- Customization of content for various roles and areas of research (Question 3b);
- Regular review and appropriate updating of content and curriculum (Question 3d);

- Expectations of periodic training for individuals with ongoing or recurrent involvement in human subjects research (Question 6); and
- Systems or procedures to ensure and document that individuals complete training (Question 7 and Question 8).

That said, we believe that these features can be developed and implemented most effectively when there is sufficient flexibility to tailor programs to accommodate the unique needs and circumstances of individual institutions and the diversity of personnel and research projects within those institutions. Accordingly, we recommend that OHRP guidance be stated in terms of objectives and desired outcomes instead of specifying how institutions should reach these objectives. It also would be useful for OHRP to make available to the research community a collection of best, as well as troublesome, practices identified in the course of OHRP reviews and enforcement proceedings.

As OHRP considers guidance regarding education and training, we hope the Office will bear in mind that training is but one component of a broader human subjects protections program and that enhancement of training is but one means to improve human subjects protections. All these components compete for institutional and agency resources, and increases in the scope of any one component may come at the expense of the others. Accordingly, we hope that OHRP guidance will focus upon those aspects of education and training that have been shown to provide substantial benefit to human subjects protections.

Thank you again for the opportunity to comment on this important issue.

Sincerely yours,



Stephanie S. Spangler, M.D.
Deputy Provost for Biomedical and Health Affairs

Cc: Maurice J. Mahoney, M.D., J.D., Executive Director, HIC
Sandra L. Alfano, Chair, HIC I

Carome, Michael A (HHS/OPHS)

From: Zuccarelli, Anthony (LLU) [azuccarelli@llu.edu]
Sent: Monday, September 29, 2008 10:51 PM
To: PSC Humansubjectstraining
Cc: Quick-Wolfe, Janice; Sarmiento, Lorraine (LLU); Halstead, Linda (LLU); Krausz, Jr (LLU)
Subject: Human Subjects Protection Training and Education

Comments on Human Subjects Protection Training and Education

(1a) This response is based on the perspectives of our institution only. We hold an OHRP-approved FWA and we have implemented OHRP recommendations on training and education.

(1b) Our institution has implemented OHRP recommendations for training and is currently engaged in a comprehensive review and expansion of its research educational program. Based on our experience, we believe that limited funding is often a key reason for delayed implementation of training recommendations. In an era of tight budgets, expenditures must be justified at multiple institutional levels. For example, when we proposed a research education coordinator position, our human resource management department required us to cite specific regulations mandating such a position. Since we receive National Institutes of Health (NIH) funding, we were able to use NIH requirements as justification. Substantial staffing costs are incurred to support educational recommendations, either to hire dedicated instructional personnel or to compensate existing administrators, educators, or investigators for assuming this additional responsibility. A second cost-driver is meeting the requirement to document and track training in a comprehensive way. Financial limitations obstruct software acquisition, such as Learning Management Systems (LMS), to assign training requirements to investigator categories, notify them of annual obligations, schedule training activities, and document fulfillment of educational requirements. At our institution, we are expanding our training offerings within the confines of existing systems, a challenge that requires a substantial investment of time and creativity. A federally mandated program, rather than the current method of government recommended and guided training, would represent a considerable unfunded mandate. It would come at a time when healthcare is stressed by decreasing reimbursement and federal grant funding is in decline.

(1c) We have not observed a failure of an institution to implement OHRP recommendations and, consequently, are unable to respond to this question.

(1d) This question presumes that a failure to accept and adapt OHRP training recommendations has been a significant factor in noncompliance with requirements for subject protection and lead to actual incidents of inadequate protection. Reality is more complex, but accepting the premise for the purpose of providing a response, we are confident that additional regulations would not be "the best mechanism to address this problem." Support for our conviction follows.

We assume that the goal of the proposed plan is to achieve greater protection for research subjects. That is the intended goal of current laws and regulations. Training and education are intuitively important for compliance with laws and achieving improved subject safety, however, there is considerable opportunity for a discontinuity between training and improved practice. One is an input, the other an outcome. Training is necessary, but not sufficient, for compliant performance and regulation of training is still further removed from subject safety. The ancient saying, "Tis many a slip between the cup and the lip," pertains here. It would be extremely difficult to devise a federal regulatory scheme for training that, given the diversity of research contexts and institutions, would invariably result in improved subject safety. We genuinely believe that education and training that reflect local conditions and incorporate institutional values will have a greater positive effect on investigator compliance and subject safety.

It is useful to note that clinical trials involving investigational drugs and devices, which may represent the most serious risks to research subjects, are already comprehensively regulated by the FDA. In response to that oversight, large pharmaceutical companies have generally assigned significant resources to training. Investigators and key personnel are routinely trained by the study sponsor on the subject protection. It seems unlikely that additional regulation would significantly improve what large pharmaceuticals have already accomplished with existing incentives.

Smaller device manufacturers, investigator-initiated and student research projects usually do not have access to the same level of resources. Since the rules and requirements are the same, the question is not whether training is important and useful, but whether an institution with limited resources, unique perspectives, and institutional insights, is in a better position to know what will be locally effective than a remote government agency.

- 2) If HHS proposed further guidance on training, from our experience, no particular group stands out as needing education more than another. Each group has a role to carry out in the process and must be informed of the implications of the decisions that are made. As stated previously, investigators for drug company-sponsored clinical trials seem to be trained more thoroughly. Nevertheless, it is difficult to document a high correlation between training time and improved performance or behavior. A regulatory scheme so detailed that it particularize the rules down to different groups or roles of individuals involved in research would be reaching even deeper into the structure and function of local institutions and conditions for control. No matter how well-intended, that option is rife with opportunities for missing the intended target. As an example, "old school" investigators are inclined to do things as they have for 30 years, in spite of training updates. Local understanding of the personalities, relationships with colleagues, and history with the institution are indispensable in crafting an education environment that will successfully reorient those entrenched attitudes. Externally formulated regulation can't do that, but will still consume institutional resources that could be used more effectively.
- 3a) Any potential further guidance or regulation should not include specific content for education and training programs since the institution is in a better position to make that determination. This, in fact, is the theme of this commentary.
- 3b) Each institution can decide their own requirements based on their observations and specific situations.
- 3c) It is reasonable to expect a minimum level of knowledge of research personnel, but how that training is organized and delivered should remain flexible.
- 3d) Some topics may not need to be updated often. Others may need to be changed periodically, especially if the underlying requirements (e.g., state or federal law) change.
- 4) The current requirements seem sufficient.
- 5) The current guidance seems sufficient.
- 6) We feel that each institution is in the best position to determine how often training should occur and the time intervals between training sessions. The institution should have flexibility in this area.
- 7) Guidance might be provided to recommend that institutions prepare and maintain written procedures, though implementing such tasks may place an excessive burden on institutions with limited administrative staff. Further, since education is typically not a "cookie-cutter" operation, the actual training program is likely to be an amalgam of online resource, live-classroom, book study, one-on-one mentoring, in-services, etc. This is difficult to document in procedures. They must either be written so generally as to provide little guidance, or consume huge resources to re-write as procedures catch-up to the "real-world" of what is happening in the institution. Since, as discussed earlier, institutions often lack dedicated funding for training, the effort to maintain documentation of training is also unfunded. At a minimum, a reliable source of funding for any additional requirements must be clearly stated.
- 8) Institutions should have the flexibility to determine what training requirements are needed and manageable since the institutions and their research vary greatly. Having mandated requirements does not seem appropriate.
- 9) Costs to an institution for implementing mandated training will be significant, especially if investigators' time is evaluated. For example, as a medium sized institution, we have approximately 3,000 investigators in our database who have received training recently. We have one FTE assigned to coordinate the educational program and we currently use CITI as the platform for our training. Next year, CITI will be charge \$1,500 for their services, which is quite reasonable. However, theirs is not a full-service LMS, so we have to manually enter the data received from CITI into a local database to track training requirements and activities. If educational requirements are not met, the study must be put on hold until they are satisfied. Though this is an effective compliance mechanism, it consumes considerable staff time and effort because CITI does not directly communicate with our database (manual entry is required) and the database does not automatically inform investigators of their educational status. Our goal is to expand research training university-wide, beyond human subject protections, to grant requirements, time and effort recording, conflicts of interest,

financial responsibilities, export controls, etc. In addition to the CITI online modules, we have regular live meetings for clinical coordinators and department administrators to discuss grant and contract issues. Training enforcement (suspending studies), routine training meetings, and live training sessions occupy at least 1.5 FTEs. Because of the caliber of personnel required, these tasks cost \$150,000 yearly in salaries and benefits. Software purchases and licenses, programming, national workshops and training sessions for staff are additional costs. Significant new requirements may require an additional 0.5 FTE and force us to purchase a LMS system. Investigators' time must be considered as a real cost, especially if new mandates are contemplated. Based upon our current activities, a modest estimate of the annual cost of our research training program is given below.

Personnel costs 1.5 FTE	\$150,000
Investigator time basic (\$50 x 4.5 hrs x 500 trainees)	112,500
Refresher course (\$50 x 1 hr x 2000 trainees)	100,000
IRB continuing education (\$75 x 1 hr x 40 members)	3,000
CITI	1,500
Software purchases, upgrades, licenses	5,000
Workshops & training for staff IRB (\$1800 x 1.5 meetings x 6 staff	16,200
Total annual cost	\$388,200

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Carome, Michael A (HHS/OPHS)

From: Liz Wool [lizwool@qd-qts.com]
Sent: Tuesday, September 30, 2008 1:05 AM
To: PSC Humansubjectstraining
Subject: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs.
Attachments: OHRP Public Comment_Education and Training _27 Sept 2008_lwoolqd-qts.com.pdf; Wool.pdf

Good day,

I forgot to add my answers to the specific questions posed by OHRP in the request for public comment.

As it is still 9/29/08 here on the west coast, I hope that you will accept this document.

Thank you!

Liz

Liz Wool, RN, BSN, CCRA, CMT
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27 September 2008

Office of Human Research Protections
Public Comment: Human Subjects Protection Training and Education

To whom it may concern:

In the last decade, clinical researchers have conducted clinical trials whereby their lack of knowledge of human subject protections embodied in Good Clinical Practices and ethical conduct for research (Belmont Report, Declaration of Helsinki) has resulted in clinical trial misconduct and subject deaths. Notably, these cases were reported in both our news media and professional publications. These cases, Jesse Gelsinger (1999, University of Pennsylvania, Gene Therapy Program) and Ellen Roche (2001, Johns Hopkins Hospital) were inspected by both the FDA and the Office of Human Research Protections (OHRP) with the identification of a broken system of clinical research oversight and human subject protection. These findings document that our 'System of Shared Responsibilities' was gravely broken at these institutions. Granted, since these occurrences, these issues have been addressed by both institutions, however, the 'broken systems' could have been prevented with proper training on human subject protections, GCP training and additional topics. Since these landmark events, clinical researchers continue to not understand their responsibilities and how to implement these responsibilities in clinical trials hence we continue to see institutional and investigational site regulatory inspections identifying significant issues in the conduct of clinical research.

Establishing mandatory training for clinical research does have precedent in both US based medical practices and the US product development regulations. Firstly, in the US Code of Federal Regulations, training and training documentation is a requirement in both Good Manufacturing Practices (21 CFR 201 and 210, QSR) and Good Laboratory Practices (21 CFR 58) for the activities and personnel employed in these non-clinical specialties. It is now time to bring the same level of requirements, standards, and performance to the GCP arena, which is much closer to ensuring subject safety than the production of investigational products and animal studies. Secondly, as a Registered Nurse, my nursing school training was multi-tiered before I was allowed to take a patient's vital signs, administer a medication, administer shots, perform venipunctures and taking a patient's intake history for their medical record. This training including the following:

1. Read about the patient's disease, disease diagnosis methods, disease treatments (medications, other therapeutic measures), potential side effects of medications and any treatments.
2. Verbally discuss with the nursing instructor the above in relation to the patient's presenting disease, as well as, concomitant illnesses and concomitant medications. This also included a requirement to understand drug-drug interactions as well.



3. Observing the performance of a therapeutic intervention, prior to performing my doing it alone (e.g. skin ulcer dressing changes, giving a shot etc.). I would have to explain, in detail, the rationale for the intervention, potential negative consequences if not performed correctly, any specific precautions to take, and a step-by-step description of the intervention I was being trained on.
4. Perform the nursing/therapeutic intervention with the nursing instructor observing me. The nursing instructor would document that I was 'qualified' to perform the specific therapeutic intervention independently.
5. Lastly, I had to pass the 'nursing board examination' to be a registered nurse and nurses are required to maintain their 'currency' with nursing and medical practice as evidenced with the continuing education requirement linked to nursing license renewal standards.

Therefore, clinical researchers need to be approaching clinical trials, and the care of our study participants, the 'subject', as equal to medical practice and ensure that professionals designated to 'care for our subjects', are trained to the same standards as non-clinical research subjects (e.g. medical practice, clinics etc). Would a physician/PhD/dentist/nurse practitioner in private practice actually delegate these responsibilities to un-qualified staff per state licensure requirements and professional liability standards? I believe not. As a professional who has held positions as a Research Nurse, Clinical Research Associate (CRA), Clinical Trial Manager, as well as in Clinical Compliance – Standards and Training, and Clinical Research Training, I continue to be concerned at the inadequate knowledge and lack of practical training (how are staff trained to obtain informed consent, identify and report AEs/SAEs, perform study procedures, review an Investigator's Brochure for safety profile review, documentation etc), for institutions, IRBs, investigators, sub-investigators, study coordinators and study personnel ranging from stand alone private practices to academic institutions.

In the training of our health care professionals, the educational approach includes self-study, classroom learning and on-the-job-training. However, with the emergence of on-line/e-learning/computer based training, many people believe that completion of such learning modules state that they are trained and qualified to conduct their role in clinical research. However, without the inclusion of on-the-job training, such on-line learning is merely the same as 'reading a textbook'. And, such a training practice for either a doctor or a nurse would not be viewed as resulting in a competent skill level for patient care (ie. qualified to care for the patient on the topic being 'read' online alone). As we move forward to guide the development of this regulatory requirement, I would like to strongly recommend that as the regulation is written, that OHRP take into consideration these requirements and most importantly 'on-the-job training' on specific topics and training documentation (i.e. training records) for deeming personnel 'qualified' to perform their assigned duties. (Wool, June 2008, *Monitor* magazine).

In closing, recommendations for training have been noted in the OHRP Determination Letters and FDA Warning Letters over the past few years (e.g. GCP, investigator responsibilities, adverse events, case histories, investigational product management and accountability, informed consent, staff training on protocol/study procedures, corrective and preventive actions for errors in research execution etc.). Requiring mandatory training for institutions, investigators, IRBs



and study staff engaged in clinical trials and under the purview of GCP can be substantiated and benchmarked to current requirements in the US CFR for GMP and GLP regulations as previously discussed. This level of regulatory requirement is needed as well in the GCP arena. Clinical researchers governed by GCP are actually 'closest' to the care of the study subject of all three of these specialties (GMP, GLP, GCP) so, why not then bring the training standards and requirements up to the same level as GLP and GMP?

Attached to this letter are specific answers to the OHRP questions for public comment.

I would be honored to be considered as a contributor to this regulation and the solutions for implementation 'in clinical research practice' as I am active in the clinical research industry (President, ACRP Northern California Chapter, DIA and SQA speaker, ACRP faculty, clinical research faculty positions at UC Berkeley, UC Santa Cruz, San Francisco State University, and program advisory board member UC Berkeley) and after 30 years in the healthcare profession and 18 years in clinical research, my passion is still strong to make a difference and be part of the solution!

Sincerely,

Liz Wool, RN, BSN, CCRA, CMT
President and CEO
QD-Quality and Training Solutions, Inc.



PART II

(2) If HHS decided to propose further guidance recommending, or a regulation requiring, that institutions implement training and education programs for certain individuals involved in the conduct, review, or oversight of human subjects research, which of the following categories of individuals should receive training and education and why: IRB chairpersons; other IRB members; IRB staff; principal investigators; others involved in the conduct of human subjects research (e.g., co-investigators, study coordinators); FWA signatory officials; human protection administrators; or any other category of individuals (please specify)? **ALL**

(3a) Should further guidance or a regulation include provisions stipulating specific content for the training and education programs? **YES** If so, what should the specific content include and why (for example, should a regulation require inclusion of any or all of the following in the content of the training and education programs: The commitments and responsibilities of the institution under the FWA; relevant ethical principles cited in the institution's FWA; relevant Federal regulations for human subjects protection; **OHRP** guidance; other applicable guidance; relevant state and local laws; institutional policies for the protection of human subjects; or other content (please specify))? **YES, per position, all of the above.**

(3b) Should the training and education recommendations or requirements differ depending upon the nature of the individual's involvement in research? If so, in what manner? **Standardized training plans and requirements per the individual's role and responsibilities.**

(3c) Notwithstanding whether training should be tailored according to an individual's role in the clinical research process, is there a minimum level of knowledge and skill that should be expected of anyone working in some aspect of the research enterprise? **Yes, ethics, GCP and technical skill for all aspects of clinical research responsibilities per the job requirements/job descriptions.**

(3d) How often should the content of the materials used for this training be updated? **Review annually and update accordingly. This is the quality systems standard that sponsors utilize for their activities.**

(4) Should further guidance or a regulation include provisions stipulating that proficiency in human subjects protection requirements be demonstrated in some way (please specify)? **Yes, per job requirements. PI – understanding and synthesizing IB information and development of informed consent, and the evaluation of the ongoing risk-benefit analysis for both his/her participation and subject enrollment. All staff – GCP and practical, tactical skills are exhibited (ae identification and reporting, SAE identification and reporting, maintaining case histories, informed consent etc).**

(5) Should further guidance or a regulation include recommendations or requirements for individuals to complete some minimum amount of training and education prior to any involvement in the conduct, review, or oversight of human subjects research? **Yes, on-the-job training, s how competency of theory and practical application and skill.**

(6) Should further guidance or a regulation include recommendations or requirements for periodic continuing training and education? If so, should the guidance or regulation stipulate a specific time interval for such periodic training and education (for example, should the



regulation require individuals to complete continuing training and education activities every 1, 2, or 3 years)? **Yes, annual GCP training.**

(7) Should further guidance or a regulation include recommendations or requirements for institutions to prepare and maintain written procedures for ensuring implementation of the training and education requirements? **Yes, SOP for employee training (1) training plans for each job/job function (2) individual employee training plan addressing regulations, procedures and on-the-job training (3) trainer qualifications (4) on – the – job trainer qualifications (5) define ‘competent’ to perform a specific job activity independent from their trainer.**

(8) Should further guidance or a regulation include recommendations or requirements for institutions to prepare and maintain written documentation that individuals covered by the regulation have completed the required training and education activities? **Yes, implement same requirements that GMP and GLP regulations require and standards that sponsors work with in the industry. Individual training plan, reviewed and updated annually and with new jobs/responsibilities are added to the plan. Please refer to ACRP June 2008 article, Good Training Practice 101: A Primer for Employee Training Plans (Wool)**

(9) If HHS decided to propose a regulation, what would the estimated costs of the regulation be to institutions in terms of infrastructure and man-hour costs? **The establishment of the quality management systems (procedures, training, QC measures, QA audits) will be a one-time charge. There will need to be a compliance standards and training function to manage development, deployment, implementation and process improvements, documentation and regulatory agency inspection support. Once implemented, it will be maintenance only and ensuring there is a QC and QA function in place.**

OHRP is interested in receiving specific information on such estimated costs from all types and sizes of institutions that hold **OHRP**-approved FWAs. **OHRP** recognizes that the HHS human subjects protection regulations extend to a wide-range of institutions, from very small organizations and businesses that employ no more than a total of 5-10 individuals, to major academic research and health centers that may have literally thousands of individuals affected by any new training and education regulation. When providing comments regarding cost estimates, please include a description of assumptions that were made for calculating cost estimated (for example, assumptions made regarding the number and types of individuals who would be required to undergo training and education, the modalities that would be used for delivering the training and education, the time it would take for covered individuals to complete initial and continuing training and education, and how often continuing training and education would need to occur). **Recommendation: Annual GCP training should be topical, and oriented to the issues at the institution and trends/patterns in GCP activities. This can be a standard topic offered via classroom, webinar. Caution with on-line learning if it is not associated with practical, on-the-job discussions or training within department for ‘relevancy’ and assurance people are able to ‘implement’ the new knowledge. Many people do not learn via on-line learning.**

Carome, Michael A (HHS/OPHS)

From: SARENA D SEIFER [sarena@u.washington.edu]
Sent: Tuesday, September 30, 2008 9:26 AM
To: PSC Humansubjectstraining
Cc: Sarena Seifer
Subject: Human Subjects Protection Training and Education

Attachments: OHRP-Comments-092808.doc



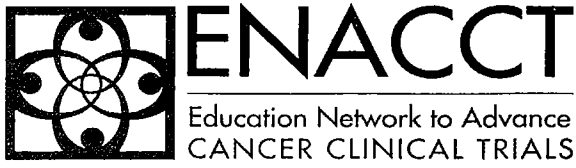
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92808.doc (553 ...)

Please see attached - this was originally sent at 3:30 pm EST on Monday September 28 and bounced back this morning as undelivered. I am trying again. Please confirm receipt. Thanks!

Sarena

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**Comments on the Implementation of Human Subjects Protection Training and Education Programs
September 29, 2008**

Submitted by:

**Education Network to Advance Cancer Clinical Trials (ENACCT) &
Community-Campus Partnerships for Health (CCPH)**

Submitted to:

**Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science
Office for Human Research Protections**

Background

The Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH) are pleased to submit comments on the Implementation of Human Subjects Protection Training and Education Programs in response to the DHHS request. ENACCT is the only national organization devoted solely to identifying, implementing and validating innovative community centered approaches to cancer clinical trials education. CCPH is the only national organization devoted solely to promoting health through partnerships between communities and higher educational institutions, using community-based participatory research, service learning, broad-based coalitions and other strategies.

Together we are spearheading a national federally funded initiative, *Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy*,¹ which is exploring the potential of employing *community-based participatory research* principles and approaches to improve multi-site, phase III cancer clinical trials. Community-based participatory research (CBPR), as defined by the Federal Interagency Working Group on CBPR² and subsequently adopted by the NIH Scientific Interest Group on CBPR,³ is “scientific inquiry conducted in communities in which community members, persons affected by the condition or issue under study and other key stakeholders in the community’s health have the opportunity to be full participants in each phase of the work, including conception, design, conduct, analysis, interpretation, conclusions and communication of results.” Our forthcoming national report⁴, to be released in October 2008, makes a number of recommendations relevant to the issue of training and education of clinical research teams and IRB members, for which OHRP is seeking public comments and guidance. These are summarized below and worded to be broadly applicable to human subjects research.

¹ *Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy* is funded by grant number 1 R13 HS016471 from the Agency for Healthcare Research and Quality, with co-funding from the National Cancer Institute. For more information, visit <http://www.enacct.org/conference/conference.php>

² Federal Interagency Working Group on CBPR. <http://www.niehs.nih.gov/translat/IWG/iwghome.htm>

³ NIH Scientific Interest Group on CBPR. http://grants.nih.gov/grants/training/esaig/cbpr_sig.htm

⁴ Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH). (2008). *Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy*. Silver Spring, MD and Milwaukee, WI. Available on the ENACCT website at <http://www.enacct.org> and on the CCPH website at <http://www.ccphe.info>

Comments

A. Need for additional guidance recommending that institutions engaged in human subjects research conducted or supported by the Department of Health and Human Services (HHS) implement training and education programs for certain individuals involved in the conduct, review, or oversight of human subjects research

We believe that additional guidance is needed to train and educate individuals involved in the conduct, review, and oversight of human subjects research. We believe this training needs to be required and needs to go beyond the content areas currently covered by the OHRP assurance training modules.

For those involved in the conduct of research (e.g., principal investigators, co-investigators, study personnel), we recommend that they be trained in these areas:

1. Engaging communities in research and optimal ways to integrate community members into research activities, including CBPR principles and approaches. This training should enable those involved in the conduct of research to:
 - a. Develop mutually beneficial, sustained partnerships with existing community infrastructure, such as primary care providers and community-based organizations. These partnerships should engage in outreach and education efforts that inform the community about research beyond any particular study. Whenever possible, research sites located in the same geographic area should collaborate in these efforts.
 - b. Engage in outreach activities with community groups, particularly those working to reduce health disparities, to educate the broader community about research beyond any particular study.
 - c. Implement training for community members to prepare them sufficiently for the research related activities they will undertake.
2. Culturally and Linguistically Appropriate Standards and Clinical Trials (CLAS-ACT): Federal officials have recently underscored the need for cultural competency training in the research setting, supporting researchers to apply CLAS standards to the clinical trials process⁵ and we agree. This training in cultural competency as it relates to study access, recruitment, and retention should enable those involved in the conduct of research to:
 - a. Implement the consent process through trained staff, including, when available and appropriate, patient navigators who can assist in the consent process at the patient's request.
 - b. Address the needs of minority, low-literacy, poor and elderly, underserved, and Limited English Proficiency (LEP) populations in the informed consent process, including the use of trained medical interpreters or a telephone language line⁶ for LEP individuals, throughout the informed consent process and when consent forms are not available in the individual's native language.
 - c. Appropriately use the OHRP-approved "short form" in the consent process.

For those involved in the review or oversight of research, (e.g., IRB administrators, members), we recommend that they have a basic of understanding of these issues, as applicable to the research application under review:

1. The disease being studied, including its standard of care.
2. The research process being proposed, be it traditional clinical research, CBPR, social and behavioral research, etc.
3. Key aspects of community outreach and accessible communication and education strategies.
4. The Belmont Report and ethical requirements for research.
5. The informed consent process.

⁵ Culturally and Linguistically Appropriate Standards And Clinical Trials. <http://www.omhrc.gov/templates/content.aspx?ID=5046> and <http://www.bcm.edu/edict/clas-act/index.htm>

⁶ 24-hour accessible interpretation services utilized in many health care institutions

For those involved in the review or oversight of research, (e.g., IRB administrators, members), we recommend that they be trained in these areas:

1. Strategies for community engagement in research, including CBPR.⁷ While IRBs do consider the local context in which research is conducted, IRBs are neither expected nor required to assess the risks and benefits of a given study to participants' communities or the broader community, and most do not make this assessment.⁸ Similarly, IRBs are neither expected nor required to assess the nature and extent of community support for the study. However, IRB examination of studies' community benefit and community support may improve overall research outcomes.¹¹
2. Appropriate community member roles on the IRB.
3. How to consider evidence of community engagement in and community support for studies seeking IRB approval.
4. Approaches to appropriately address the needs of minority, low-literacy, poor and elderly, underserved, and Limited English Proficiency (LEP) populations in the informed consent process.
5. The appropriate use of the OHRP-approved "short form."

We also recommend that specific orientation, training and mentoring be provided for IRB community (non-affiliated, non-scientific) members to help ensure they are comfortable and competent in their roles on IRBs.⁹ These members can help to ensure that language and other aspects of a research study make sense to the layperson. They can bring unique viewpoints to the IRB; nonaffiliated members are not biased by employment, and non-scientific members are not biased toward the research question.¹⁰ They can play an important role in evaluating the benefits and risks to research participants, reviewing the informed consent process to ensure participant protection, reviewing protocols, and making presentations to community groups about the role of IRBs and the importance of human subjects research.^{11, 12, 13}

There are a number of barriers to community members' participation on IRBs, including not having a clear definition and understanding of their role, and the complexity and amount of information reviewed.¹⁴ Most, community IRB members, for example, view their role solely as simplifying consent forms.¹⁵

⁷ In January 2008, Community-Campus Partnerships for Health convened a workgroup to develop a CBPR training curriculum for IRBs and REBs. For more information, visit <http://depts.washington.edu/ccph/irbhome.html> or contact Jessie Tobin at jtobin@mcw.edu

⁸ Flicker S, Travers R, Guta A, McDonald S & Meagher A. (2007). Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *Journal of Urban Health*. Published Online April 10, 2007

⁹ Schuppli CA, Fraser D. (2007). Factors influencing the effectiveness of research ethics committees. *Journal of Medical Ethics*. 33(5):294-301.

¹⁰ Hurst, M. (2001). The value of difference: nonaffiliates on IRBs provide alternative views. *Protecting Human Subjects*. Summer: 1-3.

¹¹ Grignon J Wong K and Seifer SD. (2008). Ensuring Community-Level Research Protections: Proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research. Seattle, WA: Community-Campus Partnerships for Health.

¹² Taylor, C. (2002). Community vs. enclave: the moral voice of community can be reflected in IRB composition. *Protecting Human Subjects*. Summer-Fall: 6.

¹³ Anonymous. (2001). Community representation: Broadening the perspective and value base of research ethics boards. *NCEHR Commun*. 11(1):11-4.

¹⁴ Wallwork, E. (2003). Failed community representation: Does the process inhibit full IRB participation by community representatives? *Protecting Human Subjects* (9):4, 14.

¹⁵ Sengupta S, Lo B. (2003). The roles and experiences of nonaffiliated and non-scientist members of institutional review boards. *Academic Medicine*. 78(2):212-8.

The largest study to date of non-scientific and non-affiliated IRB community members found that 47% of these individuals identified lack of education and training as a problem, and 78% wanted more intensive education and training for new members.¹⁵ Many training programs already exist, listed in Appendix A (pages 5-7), that are appropriate for community IRB members. We strongly believe that it is the responsibility of the research sponsor and/or research institution to ensure the availability of such training. We outline qualification and expectations of community IRB members in Appendix B (page 8).

Building upon reports of the National Bioethics Advisory Committee and the Institute of Medicine, we also recommend that OHRP require IRBs to be comprised of 25% community (non-scientific, unaffiliated) members who are properly oriented, trained, mentored and compensated by the IRB sponsoring institution.^{16 17 18}

B. Need for HHS development of a regulation requiring the implementation of such training and education programs

We believe that federal regulations must help to ensure that all those who are involved in the conduct, review and oversight of research are adequately educated about, and sensitized to the protection of human subjects in the specific areas above that are missing from current requirements. Training in these areas is needed so that those involved in the conduct, review and oversight of research can (a) better understand the implications of research design and recruitment plans on goals for participation; b) better assess community benefit and relevance to a proposed study; and c) assure appropriate understanding of consent process by participants. Federal regulations should require both the implementation of training and education programs and the demonstration of competence.

Contact Information for these Comments

Margo Michaels, MPH, Executive Director, ENACCT, margo.michaels@enacct.org
Sarena Seifer, MD, Senior Consultant, CCPH, sarena@u.washington.edu

¹⁶ National Bioethics Advisory Commission. (2001). Ethical and Policy Issues in Research Involving Human Participants Bethesda.

¹⁷ Institute of Medicine. (2003). *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise: Clinical Research Roundtable Workshop Summary*. The National Academies Press; Washington, D.C.

¹⁸ Additional guidelines for community IRB members can be found on page 28 of the IOM report: *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise: Clinical Research Roundtable Workshop Summary*. <http://www.iom.edu/CMS/3740/4881/12889.aspx>

Appendix A: Training Resources for IRB Members

We recommend that HHS consult and utilize these training resources when developing and implementing training requirements for IRB members, in particular community IRB members. Although a number of these resources are focused on cancer clinical research, we believe they are more broadly applicable.

NCI's CARRA Training Program

This NCI training program helps patient advocates become effective participants in the NCI peer review process. The 2 ½ day workshop curriculum is for members of its Consumer Advocates in Research and Related Activities (CARRA) program. Entitled “Preparing Consumer Advocates to Participate in Peer Review,” the training program focuses on the scientific, technical, and cultural aspects of NCI peer review and how advocates can more effectively represent the collective views of survivors, patients and family members during the grant review process. Each workshop is conducted by a multidisciplinary training team, which includes consumer advocates, university scientists, NCI staff, and training facilitators. Mock peer reviews are also conducted to demonstrate how grant applications are reviewed and scored, and how advocates address human subjects concerns during the peer review process. The NCI website includes a downloadable version of the CARRA training curriculum and additional training resources for community representatives/patient advocates.

<http://carra.cancer.gov/members/training/overview>

Coalition of Cancer Cooperative Groups' Patient Advocacy Training

The Coalition of Cancer Cooperative Groups' self-study training program, *Cancer Research: A Guide to Cancer Clinical Trials*, was developed for patient advocates nationwide. The goal of the training program is to provide education, training and ongoing professional support that will enable advocates to: effectively inform and influence the cancer clinical trial research process; stay current with issues and aspects of clinical research; and increase patient accrual to clinical trials. The training program includes six individual modules: Cooperative Groups; Cancer Clinical Trials; Drug Development; Surgical and Radiation Therapies; Protecting Research Participants; and Tissue and Its Use. The training program is available on-line and in CD format. The coalition also sponsors an annual Patient Advocate Training and is a national co-convenor of the annual “Summit Series on Cancer Clinical Trials.”

http://www.cancertrials-help.org/patient_content/pdMainContent.aspx?intAppMode=5

The Research Advocacy Network “Advocate Institute”

The Research Advocacy Network's Advocate Institute provides advocates with multiple learning modalities so they can better understand the medical research system, participant protections and scientific concepts for more effective interactions with the research world. The Advocate Institute offers on-site training programs, as well as web-based learning opportunities, including the “SkillBuilders” and “ScienceBuilders” on-line training courses.

<http://www.researchadvocacy.org/advocateInstitute/index.php>

American Association for Cancer Research (AACR) Scientist ↔ Survivor Program

The AACR Scientist ↔ Survivor Program is designed to build partnerships between the scientific and cancer survivor/patient advocacy communities. The program exposes advocates to special lay-language lectures, small group discussions and other interactions that provide a solid background in cancer research. Through the program, patient advocates develop stronger backgrounds in cancer research and related issues; keep abreast of recent advances in drug development and basic, clinical and translational cancer research; and interface with cancer scientists. <http://www.aacr.org/home/survivors--advocates/scientistharr;survivor-program.aspx>

Project LEAD

Developed by the National Breast Cancer Coalition (NBCC), Project LEAD® is a science training course designed to help breast cancer activists influence research and public policy processes. As an extensive, four-day program, Project LEAD® prepares advocates for participation in the wide range of forums where breast cancer research decisions are made. Through the training of Project LEAD®, NBCC has created an innovative model for consumer influence marked by open communication and an exchange of information among scientists, researchers, policy-makers, and consumers nationwide. Project LEAD graduates are eligible to take the advanced course: Clinical Trials Project LEAD.

http://www.stopbreastcancer.org/index.php?option=com_content&task=view&id=395&Itemid=138

C3 Research Advocacy Training Program

Colorectal Cancer Coalition (C3) sponsors an annual Gastrointestinal (GI) Research Advocacy Training. This goal of the training is to improve the ability of advocates to effectively participate in the research process. The GI Research Advocacy training is open to all advocates with a focus on GI cancers who are currently serving as patient representatives for the FDA, NCI, Cooperative Groups, Specialized Programs of Research Excellence (SPOREs), and local IRBs or DSMBs.

<http://fightcolorectalcancer.org/>

NCI's Cancer Information Service Partnership Program

NCI's Cancer Information Service has established partnerships with nonprofit, private and other government organizations at the national, regional and state levels to develop and implement training programs on cancer-related topics, including clinical trials. The CIS works with partners that have an established presence are trusted within their communities and are dedicated to serving minority and medically underserved populations.

<http://cis.nci.nih.gov/>

Project TRES

Project TRES (Training in Research Ethics and Standards), funded by NIH, is a culturally-tailored, content-appropriate, Spanish-translated research ethics curriculum that targets community health workers who assist with community-based research in Hispanic/Latino communities. Community health workers are respected members of the target community and are often involved in conducting complex research protocols. The web-based curriculum is divided into three sessions that address the purpose of research; the roles and responsibilities of those involved in research; risk and benefits; confidentiality of information; and the components of the informed consent process (e.g., recruitment, enrollment and participation).

<http://projecttres.sdsu.edu/tres/about.jsp>

NCCTG Patient Advocate Symposium

The patient advocate committee of the North Central Cancer Treatment Group (NCCTG) hosts an annual training symposium for cancer research advocates, especially those interested in working within the cooperative group structure. The symposium seeks to develop a network of community patient advocates who are knowledgeable about cancer research and clinical trials.

<http://ncctgpatientadvocates.org/home.html>

Community-Campus Partnerships for Health Curriculum on Developing and Sustaining CBPR Partnerships

This evidence-based curriculum is intended to develop a deeper understanding of the basic principles of CBPR and strategies for applying them. The curriculum includes seven units, each containing learning objectives; in-depth content information about the topic(s) being presented; examples and interactive exercises; and citations and suggested resources, selected based on their relevance and usefulness to the unit's learning objectives.

<http://www.cbprcurriculum.info>

United States Cochrane Center: Understanding Evidence-based Healthcare

The U.S. Cochrane Center is a non-profit organization, which produces and disseminates reviews of healthcare interventions and promotes clinical trials. The organization offers a free web-based course that is designed to help consumer advocates understand the fundamentals of evidence-based healthcare concepts and skills. The objectives of the course are to provide consumer advocates with the tools they need to successfully navigate the world of medical information, critically appraise research studies, influence the creation of responsible public policy in healthcare, and help the people they serve to make healthcare choices based on the best available evidence.

<http://apps1.jhsph.edu/cochrane/CUEwebcourse.htm>

SPORE Patient Advocate Research Team (PART) Program

Although the grant that funded the SPORE (Specialized Programs of Research Excellence) PART Program has ended, training materials developed through the program are available on the web, including the *Clinical Trials & People Workshop*, as well as other resources for developing research advocacy skills.

http://www.sporeadvocates.net/content/index.php?option=com_frontpage&Itemid=1

For other training resources, contact Deborah Collyar, president of PAIR: Patient Advocates In Research and former SPORE PART program director, at collyar@att.net, for other training resources.

Cancer Information and Support Network (CISN)

CISN is a grassroots organization that fosters public awareness and literacy of about the importance of clinical research. It offers a variety of trainings for community representatives/patient advocates, including:

- “Clinical Trials 101”
- “How to Read & Review a Clinical Trial Protocol”
- “Effective Advocate Participation in the Clinical Trial process”
- “How to help write good consent forms”

<http://cisncancer.org/>

Family Health International’s Research Ethics Training Curriculum

Family Health International’s (FHI) Office of International Research Ethics (OIRE) has developed a curriculum to empower community representatives to participate effectively in research activities. Developed and field-tested in eight countries, the Research Ethics Training Curriculum for Community Representatives (RETC-CR) helps community representatives to understand the research process and their roles and responsibilities as partners of the research team. The curriculum also explains the corresponding roles and responsibilities of ethics committees/IRBs and researchers. The RETC-CR addresses universal principles of research ethics, informed consent, ethics committees, and other important issues. The curriculum is available in an on-line, self-study version, as well as in print and CD-ROM format. Available languages include English, French, Spanish and Portuguese.

<http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm>

Appendix B: Suggested Qualifications¹⁹ & Expectations of Community IRB Members

From: Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH). (2008). Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy. Silver Spring, MD and Milwaukee, WI.

- Being directly affected by cancer (personally, as a caregiver, or as a member of community disproportionately affected), AND
- Having experience with cancer advocacy through activities/organizations²⁰ that go beyond a personal experience, AND
- Willing to learn more about cancer, cancer research, and how cancer affects the community
- Meaningful connection with a specific constituency affected by cancer with which he/she is able to have ongoing communication and feedback
- Genuine understanding of the specific community's/constituency's' needs
- Interest and ability to network with other organizations with an interest in cancer
- Level of comfort articulating opinions assertively and professionally among persons of all types of educational and professional backgrounds
- Interest/ability to listen, reflect, question, and respond without becoming defensive or confrontational
- Interest in gaining self-confidence to ask questions of physicians/scientists, and to disagree with them when necessary
- Ability to interact effectively with clinical and laboratory researchers
- Ability to discern the needs of the community from which they came and the needs of local research studies

¹⁹ Qualifications are not limited to educational achievement, as measured by an academic degree

²⁰ As may be demonstrated by geographic residence or place of work, connection to the disease, trial participation, or use of a particular health service

Carome, Michael A (HHS/OPHS)

From: Daniel Ford [dford1@jhmi.edu]
Sent: Tuesday, September 30, 2008 11:31 AM
To: PSC Humansubjectstraining
Cc: CLEMENCE MILLER
Subject: Human Subjects Protection Training and Education

Attachments: Letter%20Re%20Training%20FINAL[1].doc



Letter%20Re%20T
raining%20FINAL...

Attached is the letter from Johns Hopkins University School of Medicine.

Thank you

Daniel E Ford, MD, MPH
Vice Dean for Clinical Investigation
Johns Hopkins School of Medicine

September 30, 2008

Michael A. Carome, M.D., Captain
U.S. Public Health Service
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

VIA Electronic Delivery

Re: Human Subjects Protection Training and Education

Dear Dr. Carome:

This comment letter is submitted by Johns Hopkins Medicine, (“JHM”), which comprises The Johns Hopkins University School of Medicine and Johns Hopkins Health System. JHM appreciates the opportunity to comment on the questions related to human subjects protection training and education presented by the Office for Human Research Protections (“OHRP”) in the *Federal Register* on July 1, 2008.

JHM strongly endorses and supports OHRP’s viewpoint that research training is necessary to ensure the safety and protection of human subjects. As one of the leading research institutions in the United States, JHM is deeply committed to the protection of human research subjects, and our commitment is reflected in the scope and substance of our research training program.

At JHM, human subjects research compliance training and certification is required, not only for all investigators, whether full or part-time, who conduct research on human participants, but also for those investigators’ research staffs. JHM also requires that our institutional review board (“IRB”) members, management, and staff undergo formal compliance training.

Our training requirements include courses in human subjects research, conflict of interest, and the HIPAA Privacy Rule (with an emphasis on the Rule’s requirements for research). In addition, all JHM principal investigators with active IRB-approved protocols must complete our Course on Research Ethics (the “C.O.R.E.”). The C.O.R.E. is a half-day program consisting of lectures and workshops on protocol development and design, informed consent, and scientific

integrity and mentorship. Eventually, all faculty participating in human subjects research will be required to complete C.O.R.E. training.

JHM has invested significant resources (in excess of six figures) and staff time to develop these courses and the web-based tracking system that enables our IRB's administrative staff to verify course completion when protocols are submitted to the IRB office. Our course materials address applicable state and federal requirements but also emphasize considerations that are specific to our complex research enterprise. The flexibility we enjoy under current research regulations to evolve and adapt our training program is critical, because we continually reassess our training needs and revise our courses to meet new training objectives.

With respect to the specific questions presented by OHRP in the July 1, 2008 *Federal Register*, we are pleased to provide the following responses to several of the enumerated points:

(3a) Should further guidance or a regulation include provisions stipulating specific content for the training and education programs?

We believe that each research institution is in the best position to tailor and implement training and education programs that meet the specific needs of that institution while protecting the human subjects of its research. The existing Federal guidelines and regulations serve to provide a structure around which each institution may develop its own training and education programs.

We believe that effective training must address not only the federal requirements, but also local law and institutional policy. Institutions face a difficult challenge in presenting this complex mix of content to busy learners in an efficient, effective manner, and different institutions have created different – but equally satisfactory – solutions to this problem.

Other variables, including the size and budget of an institution, the level of responsibility assigned to each researcher and research team staff member, and the type of research being conducted (*i.e.* social science or epidemiology research versus primarily clinical trials) will all influence the scope and content of a given institution's training program. If OHRP were to dictate specific content for every training program, we believe that the resulting regulations would of necessity be either overly general or excessively detailed.

(5) Should further guidance or a regulation include recommendations or requirements for individuals to complete some minimum amount of training and education prior to any involvement in the conduct, review, or oversight of human subjects research?

We believe institutions should remain empowered to design specific training programs that best protect their specific study populations and educate their research personnel. OHRP should not attempt to quantify training requirements.

Although we would not support further regulation in this area, we do agree that OHRP should recommend each institution adopt policies to ensure that all research personnel are trained. Because it can be very expensive and time-consuming to develop and implement

training programs in-house, OHRP could provide a service to the research community by endorsing, or by making available online, publicly-available training programs that address the content of concern to OHRP.

(6) Should further guidance or a regulation include recommendations or requirements for periodic continuing training and education?

We agree that it would be reasonable for OHRP to recommend continuing training and education. The human subjects research arena continues to evolve, and the people who serve on institutional review boards or conduct research must keep abreast of the changes at intervals sufficient to assure the best review and oversight of research.

We do believe that prescribing uniform re-training standards at the federal level would be unworkable because of the variables mentioned above (size and budget of institution, staff responsibilities and type of research), and because any re-training standard must vary according to the depth and intensity of an institution's initial training.

(7) Should further guidance or a regulation include recommendations or requirements for institutions to prepare and maintain written procedures for ensuring implementation of the training and education requirements?

Research institutions are responsible for ensuring that their institutional review boards and researchers are in compliance with Federal human subject research requirements, and each institution must determine how best to satisfy compliance requirements. Overly prescriptive mandates for written procedures could actually divert valuable time and resources from training and compliance efforts.

(8) Should further guidance or a regulation include recommendations or requirements for institutions to prepare and maintain written documentation that individuals covered by the regulation have completed the required training and education activities?

We believe that research institutions appreciate the importance of documenting completion of training requirements, but procedural and technical solutions to tracking and documentation vary widely, reflecting variations in the size and sophistication of research institutions. We fear that for some institutions, uniform federal requirements would impose unnecessary costs upon an already overburdened compliance infrastructure. OHRP could, however, provide a service to the research community by making tracking software or systems available on-line, or by working through the Department of Health and Human Services to provide research compliance infrastructure development grants to institutions for training purposes.

Again, we appreciate the opportunity to provide these comments. If you have any questions or would like additional information, please contact me at (443) 287-4234 or dford@jhmi.edu or please feel free to contact Jennifer Kulynych, JHM IRB Counsel, at (410) 955-7949 or jkulynyl@jhmi.edu.

Sincerely,

Daniel E. Ford, MD, MPH
Vice Dean for Clinical Investigation
The Johns Hopkins University School of Medicine

Carome, Michael A (HHS/OPHS)

From: SARENA D SEIFER [sarena@u.washington.edu]
Sent: Tuesday, September 30, 2008 12:15 PM
To: PSC Humansubjectstraining
Cc: Sarena Seifer
Subject: Human Subjects Protection Training and Education

Attachments: FinalResearchEthicsCallSeriesReport.pdf



FinalResearchEthics
CallSeriesR...

Thanks Mike! I'm also attaching a report cited in our comments - please share with others at OHRP who may be interested.

Thanks again,

Sarena

On Tue, 30 Sep 2008, PSC Humansubjectstraining wrote:

> Your email was received. Thanks for submitting comments.
>
> Mike Carome
>
> -----Original Message-----
> From: SARENA D SEIFER [mailto:sarena@u.washington.edu]
> Sent: Tuesday, September 30, 2008 9:26 AM
> To: PSC Humansubjectstraining
> Cc: Sarena Seifer
> Subject: Human Subjects Protection Training and Education
>
> Please see attached - this was originally sent at 3:30 pm EST on
> Monday September 28 and bounced back this morning as undelivered. I
> am trying again. Please confirm receipt. Thanks!
>
> Sarena
>
> *****
> **
> *****
> Community-Campus Partnerships for Health promotes health (broadly
> defined)
> through partnerships between communities and higher educational
> institutions.
> Become a member today at www.ccph.info
>
> Join us for CCPH's 11th Conference, April 29-May 2, 2009 in Milwaukee,
> WI!
> Conference proposals are due October 10, 2008 - see www.ccph.info for
> details
> *****
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The background of the cover features a large, stylized graphic of a circle containing numerous human figures. Each figure is composed of simple geometric shapes: a vertical line for the body, two diagonal lines for arms, and a small circle for a head. The figures are scattered throughout the circle, some appearing to be in motion or interacting. The overall aesthetic is clean and modern, using a grayscale color palette.

Ensuring Community-Level Research Protections
Proceedings of the 2007 Educational Conference Call Series
on Institutional Review Boards and Ethical Issues in Research

Citation

Grignon J, Wong KA and Seifer SD. Ensuring Community-Level Research Protections. Proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research. Seattle, WA: Community-Campus Partnerships for Health, 2008.

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About the Organizations That Supported This Report

Community-Campus Partnerships for Health promotes health (broadly defined) through partnerships between communities and higher educational institutions. Founded in 1996, CCPH is a growing network of over 1,700 communities and campuses across North America and increasingly the world that are collaborating to promote health through service-learning, community-based participatory research, broad-based coalitions and other partnership strategies. What ties CCPH members together is their commitment to social justice and their passion for the power of partnerships to transform communities and academe. CCPH advances its mission by disseminating information, providing training and technical assistance, conducting research and evaluations, developing and influencing policies, and building coalitions. Learn more about CCPH at <http://www.ccpb.info>

The Tuskegee University National Center for Bioethics in Research and Health Care promotes racial and ethnic diversity in the field of bioethics and in public debates about bioethical issues. Established in 1999, its mission is to promote equity and justice in health and health care. The Bioethics Center is the nation's first bioethics center dedicated to addressing bioethical issues of importance to African Americans and other underserved populations. It is also the only bioethics center at a Historically Black College and University. The Bioethics Center carries out its mission by conducting education and training programs, fostering respectful community partnerships, advancing interdisciplinary research, and advocating public policies that improve the health and health care of all Americans, particularly the underserved. Learn more about the Bioethics Center at <http://www.tuskegee.edu/Global/category.asp?C=35026>

Acknowledgements

CCPH and the Bioethics Center thank these individuals who were instrumental in providing support for the development of the call series: Bill Freeman, Northwest Indian College; Sherril Gelmon, Portland State University; Mei-Ling Isaacs, Papa Ola Lokahi; and Elda Railey and Mary Lou Smith, Research Advocacy Network. They also extend a special thanks to Lisa Moy for assistance in gathering photos for the report, along with the generous contributions made by moderator Vanessa Northington Gamble and each of the speakers.

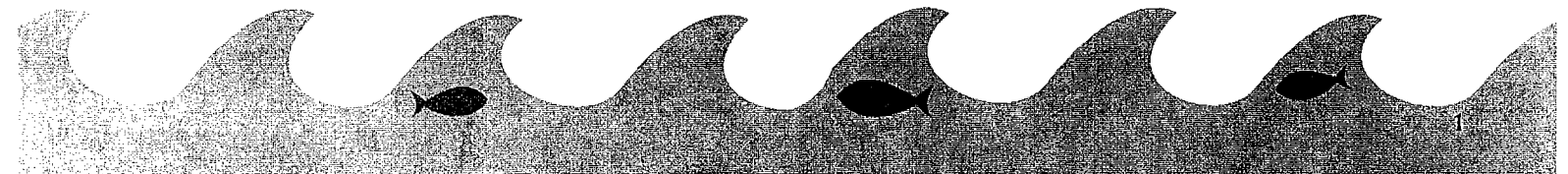
Continuing the Conversation

CCPH and the Bioethics Center invite anyone interested in community-based participatory research (CBPR) and research ethics issues to join our ongoing electronic discussion group. For more information, visit CCPH's CBPR & Research Ethics Webpage at <http://www.ccpb.info>



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Introduction

Community-Campus Partnerships for Health (CCPH) and the Tuskegee University National Center for Bioethics in Research and Health Care (the Bioethics Center) sponsored an Educational Conference Call Series on Institutional Review Boards (IRBs) and Ethical Issues in Research that took place between February 2007 and June 2007, which advanced their shared goal of meaningfully involving communities in decisions made about every aspect of research. The call series was intended to increase understanding of the role of IRBs and other mechanisms for assuring that human subjects research is ethical and appropriate – both at individual and community levels.

The idea of the call series grew from observations by CCPH – through its conferences, workshops and electronic discussion groups – that community members and researchers engaged in community-based participatory research (CBPR) were grappling with a number of challenges related to the research ethics review process. These included concerns about inconsistent community membership on IRBs, difficulties gaining IRB approval for studies employing CBPR approaches, and conflicts between the protection of individuals participating in research and the protection of communities in which research takes place. Reinforcing these observations were related concerns being raised in the peer-reviewed literature:

Community IRB Members & Their Role on IRBs: The inconsistency of community representation on an IRB through a non-affiliated or non-scientific member is prominent in the literature. In a study by DeVries and Forsberg (2002), the authors found that the majority of IRBs they examined did not meet the National Bioethics

Advisory Commission recommendations that non-scientists should compose at least 25% of membership and at least 25% of members should be nonaffiliated with the institution.¹ Even with the appropriate representation of nonaffiliated and scientific members, also known as community members, their roles are often unclear and they may not feel respected. Dyer argues that in order for the participation of the community member to be effective, their roles must be clear.² Sengupta and Lo found that many lay members have felt that scientists often disrespected their opinions and that their presence was tolerated because of a federal mandate.³ Moreover, the authors found that only 22% of the lay participants in their study had formal training, and those who did have training felt it gave them confidence in their role as community IRB member. The literature demonstrates that most IRBs may not have the recommended number of community members, and even with the requisite membership, community members may not have the necessary tools to fulfill their role.

Tensions Between CBPR and IRB Review: The Belmont principles that guide IRB review of human subjects research do not appear to cover the scope of ethical considerations that arise in CBPR, and thus the IRB's application of these principles may not provide a relevant or thorough ethical analysis. IRBs, designed to protect the rights and welfare of individual study participants, are neither expected nor equipped to protect the rights and welfare of communities involved in research. CBPR is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR also begins with a research topic of importance to the community and has the aim of combining knowledge

