Carome, Michael A (HHS/OPHS)

From: Carome, Michael A (HHS/OPHS)
Sent: Friday, August 08, 2008 2:15 PM
To: PSC Humansubjectstraining
Subject: FW: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs

-----Original Message-----
From: Drew, Glen D (HHS/OPHS)
Sent: Fri 8/8/2008 1:33 PM
To: Carome, Michael A (HHS/OPHS)
Subject: FW: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs

Mike - I've received a couple such comments, and will forward them in case they don't reach you directly.

Glen

-----Original Message-----
From: Robert McLaughlin [mailto:RMcLaugh@nccc.org]
Sent: Friday, July 11, 2008 11:35 AM
To: Drew, Glen D (HHS/OPHS)
Subject: RE: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs

Michael A. Carome, M.D., Captain,
U.S. Public Health Service, OHRP
1101 Wooton Parkway, Suite 200
Rockville, MD 20852

July 10, 2008

Re: Human Subjects Protection Training and Education

To whom it may concern:

I write to respond to the request for information and comment issued on July 3, 2008 regarding the implementation of Human Subjects Training and Education Programs, and thank the Office of Human Research Protections
(OHRP) for the opportunity to do so.

In lieu of drafting a recommendation or regulation at this time, I urge OHRP to instead consider use of its resources to provide education opportunities and training materials as broadly and as inexpensively as possible. Through participation in the Northern California (NorCal) IRB Consortium, a group of IRB administrators and professionals who meet quarterly to discuss topics and issues of common interest, and through serving as a moderator for a panel entitled "IRB: Nuts and Bolts" at the OHRP Open Forum, "Thinking Outside the Box: Addressing the Challenges of Human Subjects Protection in 2008", it is my firm view that IRB professionals and board members are unusually dedicated, thoughtful, motivated, and detail-oriented people. For the past three years, it has been my pleasure to work with and among them. Insofar as we share ongoing needs for training and education, neither a regulation nor a recommendation has been necessary to identify needs for training or to motivate attention to IRB education. Similarly, I do not expect that a regulation or a recommendation at this time would result in an increase in the budgets with which my colleagues and I work to achieve compliance with regulations for human subjects protection. Rather, I believe research institutions would generally expect IRBs to achieve compliance with existing resources.

Participation in the NorCal IRB Consortium has also exposed me to the diversity of scientific disciplines, institutions, and researchers that are engaged in human subjects research. While I might quibble with some particular details of the regulations that we all share, this exposure has demonstrated for me that the regulations work remarkably well for the level of generality at which they apply. In complement and in contrast to the regulations, training and education that is very specific and suited the context, science, and research portfolio of an institution engaged in human subjects research is best. It would be difficult to capture the concept of such training in regulatory text that might involve verification and enforcement provisions. At the Northern California Cancer Center (NCCC), for example, where the research portfolio consists of epidemiologic studies and public health interventions regarded as minimal risk studies, we require the recently revised NIH on-line module for IRB members and researchers alike. We also rely heavily on the meetings themselves, the staged introduction of new members, and the periodic circulation of bioethics and privacy literature and cancer science materials-including numerous articles from the Science Times section of the New York Times-to keep our IRB well-informed and well-suited to the task at hand. This approach would not be appropriate or adequate for an institution conducting clinical trials of a heightened risk profile, and yet it has been our experience in multi-sited, collaborative studies that such institutions do not give the same type and depth of attention to study materials that our IRB does. The differences do not indicate non-compliance with or disregard for the regulations, but rather different approaches to interpretation and implementation. These differences do, however, indicate that the appropriateness of the education and training that might be required by an OHRP recommendation or regulation would emerge as a major issue in practice and in rule enforcement.

Regulation of education and training also presents the potential problem of an additional burden to IRB participation that might fall hard on volunteer members of IRBs versus, for example, faculty members who may serve in exchange for course relief in their teaching loads, and it would be very hard to craft mandatory training modules of uniformly high applicability and quality.

Therefore, it is my strong recommendation that OHRP issue neither a regulation, nor a recommendation at this time, but instead endeavor to create the maximum number of opportunities for education and training with broad accessibility to the IRB community. The "Thinking Outside the Box" Open Forum earlier this year in Sacramento, California was terrific, but expensive, and too expensive for my Department to cover registration for all IRB members and interested researchers. PRIM&R webinars are similarly focused and also excellent as a model for delivering training and education.

In short, I believe that further regulation in the area of human subjects protection education and training is not likely to make a significant improvement to human subjects protection; education and training will, however, command that direct result, and I applaud OHRP efforts to pursue it.

The opinions and comments of this letter are my own, and do not reflect the position of the Northern California Cancer Center or its IRB for which I serve as the IRB Administrator. I thank you for your consideration.

Sincerely,
Robert H. McLaughlin

Robert H. McLaughlin, J.D., Ph.D.
Legal and Regulatory Affairs Officer
Northern California Cancer Center
510-608-5140
rmclaugh@nccc.org

-----Original Message-----
From: Office for Human Research Protections (OHRP) [mailto:OHRP-L@LIST.NIH.GOV] On Behalf Of Glen Drew
Sent: Thursday, July 03, 2008 10:48 AM
To: OHRP-L@LIST.NIH.GOV
Subject: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs

The Office for Human Research Protections (OHRP), Office of Public Health and Science is

seeking information and comments from affected entities and individuals about (a) whether OHRP should issue 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, or (b) whether HHS should develop a regulation requiring the implementation of such training and education programs. This request for information and comment stems from the 1998 report from the HHS Office of Inspector General (OIG) recommending that Federal requirements be enacted to help ensure that investigators and institutional review board (IRB) members be adequately educated about, and sensitized to, human subjects protections. More recently, the Secretary's Advisory Committee on Human Research Protections (SACHRP) recommended that OHRP require institutions to ensure that initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials. The implementation of such training and education programs might help to ensure that individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federalwide Assurances (FWAs) understand and meet their regulatory responsibilities for protecting human subjects.

Submit written or electronic comments by September 29, 2008. Comments may be submitted by any of the following methods: (1) E-mail: humansubjectstraining@hhs.gov. Include "Human Subjects Protection Training and Education" in the subject line; (2) Fax: 301-402-2071; (3) Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received within the public comment period, including any personal information, will be make available to the public upon request.

The notice can be accessed at: http://www.hhs.gov/ohrp/documents/fedreg20080701.htm or http://www.hhs.gov/ohrp/documents/fedreg20080701.pdf.

FOR FURTHER INFORMATION CONTACT: Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail Michael.Carome@hhs.gov

Carome, Michael A (HHS/OPHS)

From: Embry, Alan (NIH/NIAID) [F]
Sent: Wednesday, August 20, 2008 4:37 PM
To: PSC Humansubjectstraining
Subject: PO/human subjects

To Whom It May Concern;

I am a new program officer in a non-clinical branch but many of my grants have a human subjects component. This is turning out to be the hardest part of my job because I often do not know the rules and have to find the right person to ask. I would be highly in favor of human subjects training from a program officer standpoint.

Thanks,
Alan

Alan Embry, Ph.D.
Biologist/Program officer
Pathogenesis and Basic Research Branch, BSP
Division of AIDS, NIAID, NIH, DHHS
6700-B Rockledge Drive, Room 4150
Bethesda, MD 20892
Phone: (301) 435-3751
Fax: (301) 402-3210

Carome, Michael A (HHS/OPHS)

From: Judy Hayes [Jhayes@DCHSYSTEM.COM]
Sent: Friday, August 29, 2008 2:22 PM
To: PSC Humansubjectstraining
Subject: "Human Subjects Protection Training and Education"
Attachments: OHRP Response re education-training requirement.doc

To Whom It May Concern:

Please see attached response to OHRP's request for information and comments.

Judy N. Hayes
Administrative Assistant
DCH Health System
(205) 759-7796
Fax (205) 750-5204

DCH Health System®

Response to OHRP's Request for
Information and Comments on the Implementation of
Human Subjects Protection Training and Education Programs

August 29, 2008

TO: Michael A. Carome, M.D., Captain
U.S. Public Health Service, OHRP
Via Email: humansubjectstraining@hhs.gov

FROM: Janet Teer, J.D.
DCH Health System Institutional Review Board Signatory Designee
jteer@dchsystem.com; (205) 759-7600

The DCH Health System IRB appreciates the opportunity to comment on SACHRP's recommendation that OHRP require institutions to ensure that initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials. We agree that these individuals should understand and meet their regulatory responsibilities for protecting human subjects, but are concerned that a mandatory method of education would unduly burden small/community hospital IRBs.

To that end, we respectfully request the OHRP add to consideration the following points.

- Financial impact on small IRBs/community hospital IRBs
- Possible hardship on physicians and working community members leaving jobs for outside education/training
- Possibility of IRB members being provided information (articles, conference material brought back by one member to the group, etc.) to be allowed as education/training
- Possibility of OHRP making written material or videos available at little or no cost that would count as education/training
- Possibility of selected individuals receiving training and then educating other IRB members, with appropriate documentation

We look forward to the OHRP's decision in this matter.

jnh

Carome, Michael A (HHS/OPHS)

From: Henry Robert Kolb [kolbb@gcrc.ufl.edu]
Sent: Tuesday, September 02, 2008 12:27 PM
To: PSC Humansubjectstraining
Subject: "Human Subjects Protection Training and Education"

I would like to express my enthusiastic support on behalf of **Requiring** "Human Subjects Protection Training and Education"; and I encourage OHRP to issue guidance recommending institutions implement training and education programs for key individuals involved in the conduct, review, or oversight of human subjects research

As a Research Subject Advocate I feel strongly that the implementation of training and education programs will help to ensure individuals involved in the conduct or review of human subjects research understand and meet their regulatory responsibilities for protecting human subjects.

--

H. Robert Kolb RN,BS,CCRC
Coordinator Research Programs/Services
Research Subject Advocate
General Clinical Research Center
University of Florida
Phone: 352-265-0680 ext 43715

Carome, Michael A (HHS/OPHS)

From: Hobin, Jennifer [jhobin@faseb.org]
Sent: Wednesday, September 03, 2008 12:21 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education
Attachments: OHRP RFI.09.03.08.pdf

Dear Dr. Carome,

Thank you very much for the opportunity to comment on the Office of Human Research Protections' *Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs.* Please find attached comments from the Federation of American Societies for Experimental Biology (FASEB). Please do not hesitate to contact me if you would like additional information.

Sincerely,
Jennifer Hobin
<<OHRP RFI.09.03.08.pdf>>
~~~~~~

Jennifer A. Hobin, Ph.D.
Senior Science Policy Analyst
Office of Public Affairs
Federation of American Societies for Experimental Biology
9650 Rockville Pike, Bethesda, MD 20814-3998
Phone: 301-634-7650; Fax: 301-634-7651
Email: jhobin@faseb.org
~~~~~~

FASEB

Federation of American Societies for Experimental Biology

— Quality Life Through Research —

Member Societies

The American Physiological Society

American Society for Biochemistry and Molecular Biology

American Society for Pharmacology and Experimental Therapeutics

American Society for Investigative Pathology

American Society for Nutrition

The American Association of Immunologists

American Association of Anatomists

The Protein Society

Society for Developmental Biology

American Peptide Society

Association of Biomolecular Resource Facilities

The American Society for Bone and Mineral Research

American Society for Clinical Investigation

Society for the Study of Reproduction

Teratology Society

The Endocrine Society

The American Society of Human Genetics

Society for Gynecologic Investigation

Environmental Mutagen Society

International Society for Computational Biology

American College of Sports Medicine

President

Richard B. Marchase, Ph.D.
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marchase@uab.edu

9650 Rockville Pike
Bethesda, MD 20814-3998
Telephone (301) 634-7090
Fax (301) 634-7049
http://www.faseb.org

September 3, 2008

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

BY ELECTRONIC MAIL TO: humansubjectstraining@hhs.gov

Re: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs

Dear Dr. Carome:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the Office of Human Research Protections' (OHRP) *Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs.* As an organization representing 21 scientific societies and over 80,000 biomedical researchers, FASEB recognizes the profound importance of protecting human research participants. We affirm that all individuals involved in the conduct, review, or oversight of human subjects research must be knowledgeable of, and in compliance with, human subjects protections requirements. We also believe that institutions should be required to implement human subjects protections training and education programs for investigators, designated institutional officials, human protections administrators, institutional review board (IRB) members and staff, and others involved in this type of research.

OHRP should not, however, impose additional human subjects protections training and education requirements on principal investigators and other key study personnel funded by the National Institutes of Health (NIH). These individuals are already obligated to complete such training as a condition of grant funding and/or IRB approval, and institutions have developed a variety of excellent programs to enable them to do so. New training requirements would add to the many administrative burdens already shouldered by investigators while doing little to improve the protection of research participants. We note also that training is a requirement for NIH-funded individual investigators whereas it is only recommended for IRB members and other personnel.

In our view, research participants would be better served if OHRP focused its efforts on improving compliance with existing human subjects regulations. To that end, OHRP should continue to require IRBs to conduct periodic reviews of human subjects research performed at their institutions and report incidences of

noncompliance to OHRP. In addition, FASEB encourages OHRP to reaffirm its recommendation that institutions conduct internal audits of their human subjects protections practices to ensure they are in compliance with all applicable regulations. This internal oversight would not only encourage individuals involved in human research to adhere to regulations, but it would help OHRP to align training and education requirements with the needs of institutions and their personnel.

OHRP could also enhance the protection of research participants by ensuring that all institutions have the ability to develop effective human subjects protections training and education programs. We recognize that it may be a challenge for institutions lacking in resources or a history of involvement in human research to develop training programs on their own. These institutions would benefit from the ability to use or build upon the excellent programs that have been created by other organizations. To that end, we recommend that OHRP highlight programs that could serve as models for the type of training necessary to safeguard research participants. OHRP could accomplish this by collaborating with the Regulatory Working Group of the Clinical and Translational Science Award consortium, which is working to identify and disseminate best practices related to clinical research regulation compliance, including human subjects training.

Human subjects training needs differ depending on the nature of an individual's involvement in research (e.g., principal investigator compared to IRB chairperson) as well as the type of research in which they are involved (e.g., patient-oriented research compared to human tissue research). It is not necessary or advisable, therefore, to impose identical training requirements on all individuals engaged in clinical research. Any new training and education policies implemented by OHRP should be flexible enough to accommodate the diverse training needs of the clinical research community.

Thank you for the opportunity to respond to this request for information. Please do not hesitate to contact me if FASEB can be of further assistance to you.

Sincerely,

Richard B. Marchase

Richard B. Marchase, Ph.D.
FASEB President

UNIVERSITY OF
SOUTHERN MAINE
Office of
Research Compliance

Michael A. Carome, M.D.
Captain, U.S. Public Health Service
OHRP 1101 Wootton Parkway
Suite 200
Rockville, MD 20852

4 September 2008

Re: Human Subjects Protection Training and Education

Dear Dr. Carome:

The Provost, the Institutional Review Board, and the Office of Research Compliance of the University of Southern Maine strongly support HHS developing a regulation requiring the implementation of training and education programs for certain individuals engaged in the conduct, review or oversight of human subjects research.

In light of the dicta in *Washington University v. Catalona et al.*, a regulatory requirement is more likely to bring about the desired change than additional OHRP guidance. The 8th Circuit Court of Appeals let stand a trial court decision which included language effectively deeming OHRP guidances as "merely present[ing] and opinion" and "not legally binding upon" institutions engaged in research. In light of Judge Limbaugh's assessment of OHRP guidances, even those OHRP deems mandatory, a regulation is required to bring about the necessary change.

Ethical standards would seem to require institutions to engage in training and education exercises without a formal mandate. However, in an era of resource scarcity, this does not seem to happen. Given the totality of the circumstances, the judicial perspective advanced in the *Catalona* case and the fiscal realities of the present research environment, education seems to need to be required rather than urged.

P.O. Box 9300, Portland, ME 04104-9300
(207) 780-4268, TTY (207) 780-5646, FAX (207) 780-8405
www.usm.maine.edu
A member of the University of Maine System

Leading institutions already require such training through internal policy practices. However, not all research is done through leading institutions. Providing a uniform expectation of training and education will advance the interest of protecting participants in human subject research.

Sincerely yours,

William R. Harrison, MA JD CIP CIM
Director
wharrison@usm.maine.edu
207-780-4684

Carome, Michael A (HHS/OPHS)

From: Gullekson, Sylvia [sjgullekson@saintfrancis.com]
Sent: Friday, September 05, 2008 9:08 AM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education
Attachments: Response to OHRP Request for Comments - Education.doc

Comments in response to OHRP request -
<<Response to OHRP Request for Comments - Education.doc>>

Sylvia Gullekson, BSN, CIP
Human Protection Administrator
Saint Francis Health System
(918) 494-2440
sjgullekson@saintfrancis.com

Response to OHRP Request for Information and Comments – July 1, 2008 Federal Register

Q: Should HHS develop a regulation requiring the implementation of such training and education programs. **Comment: YES** - Guidelines do not have enforcement capability.

OHRP specifically seeks comment on the following questions.

(1a) Have institutions holding **OHRP**-approved FWAs routinely implemented **OHRP**'s recommendations? **Comment:** Our IREB requires CITI basic training and a refresher course every 2 years for IREB members / staff, investigators / key research personnel. There are some that argue this should not be a requirement because it is not in the regulations. Additional educational material is provided but not required: monthly newsletters "Clinical Trials Administrator" and "IRB Advisor". System HPA provides additional educational updates and information as needed or requested.

(1d) Would it be better if **OHRP** instead issued additional guidance regarding training and education programs)? **Comment: No** - Additional guidance will not work. There will always be those that will only do what is required.

(1e) Are there other sound reasons for developing further guidance or a regulation regarding education and training, and if so, what are they? **Comment: YES** -A common reason for deviations is "I didn't understand" or "I didn't know". Most do not know what they don't know. Having a better understanding of what is required may help prevent or minimize adverse events and facilitate the protection of the rights and welfare of human subjects.

(2) Which of the following categories of individuals should receive training and education and why?: IRB chairpersons; other IRB members, IRB staff, principle investigators and others involved in the conduct of h.s. research (e.g., co-investigators, study coordinators), FWA signatory officials; human protection administrators - **Comment: YES, all of these should receive training and education!** It is important to include "key research personnel".

Any other category of individuals (please specify) - **Comment:** It is important for hospital managers and directors to understand what activities require IREB review, how research could impact their department, as well as, what may or may not be delegated to non-research staff.

(3a) Should further guidance or a regulation include provisions stipulating specific content for the training and education programs? If so, what should the specific content include and why (for example, 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; OHRP guidance; other applicable guidance; Relevant state and local laws; and Institutional policies for the protection of human subjects; or other content (please specify) **Comment: YES, include all of the above.** Our CITI training includes an institutional page with relevant state and local laws and institutional requirements. Training should include an outline of institutional HRPP p&p that are in addition to IREB p&p related to the review and conduct of research, i.e. institutional efforts for communication, interactions, collaboration, training and continuing education, QI / QA activities, and requirements for reporting of research misconduct.

(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?
Comment: YES - Training and education should be customized to the individual's involvement. Example: CITI training is individualized at our institution with 4 Learner Groups: BMR investigators, SBR investigators, Data and Specimens Only, and IREB members.

(3c) Not withstanding 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? **Comment: YES**

(3d) How often should the content of the materials used for this training be updated?
Comment: Materials should be continuously updated.

(4) Should further guidance or a regulation include provisions stipulating that proficiency in human subjects protection requirements be demonstrated in some way (please specify)?
Comment: YES - Testing should be provided at the end of each module and a passing grade should be required.

(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? **Comment: YES**

(6) Should further guidance or a regulation include recommendations or requirements for periodic continuing training and education? **Comment: YES**
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)? **Comment: YES** - every 2 years.

(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? **Comment: YES**

(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? **Comment: YES**

(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? **OHRP** is interested in receiving specific information on such estimated costs of institutions that hold **OHRP**-approved FWAs.
Comment: We average185 active research projects. Approximately 160 individuals are involved in the conduct or review of research. A full time HPA oversees the HRPP for the System and all its entities. This includes training, education, communication, interactions, collaboration with entity HPA's, IREB Coordinators, Institutional Officials and researchers. HRPP activities include:

- Maintaining access to CITI training, notification of due dates, notification of completion. Course completed: 70 in 2006; 89 in 2007; 93 in 2008 + 17 anticipated by the end of 2008.
- Distribution of 2 newsletters (Clinical Trial Administrator and IREB Advisor) under a site license agreement to over 100 individuals under the auspices of our system.
- Maintaining documentation of training and education provided by the SFHS HPA.
- Maintaining information related to human research protections on our intranet.
- Monthly education meetings with Entity HPA's and IREB Coordinators.
- Ongoing training and mentoring of new IREB Coordinators.
- Overseeing compliance for FWA renewals and updates for SFHS and all its entities.
- Serving as a regulatory resource and a consultant for QI / QA activities including developing effective corrective / preventive actions plans when needed.

Analysis of annual costs:
Number X hours X cost/hr = total cost for 160 individuals time for completion of training and continuing education.
System HPA = full time FTE
CITI subscription = $1250
Monthly newsletters subscription / site license = $2400
PRIM&R and / or Regional Conferences = $5733

Carome, Michael A (HHS/OPHS)

From: Connolly,Pamela A [pconnoll@UFL.EDU]
Sent: Monday, September 08, 2008 1:13 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection,Training and Education

I strongly believe Investigators, coordinators, Sub-Investigators on down the line should be trained and it should be tracked.

Pam Connolly, RN
Research Nurse & GCRC Nurse
University of Florida
Community Health & Family Medicine
Phone #- 265-0441 ext. 40508
Fax # 265-9479
Beeper # 413-7933
PConnoll@ufl.edu

Carome, Michael A (HHS/OPHS)

From: goddesslisa@hawaii.rr.com
Sent: Saturday, September 13, 2008 2:44 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection

Dear Sir / Ma'am:

It has been my experience that although many organizations realize the need to educate those involved in research within their walls, they are less likely to support much training – the excuse is that there are no funds. It is not seen as a benefit, a way to reduce risk and increase efficiency. It is seen as a cold expense.

Unfortunately, these types of organizations do not take federal regulations seriously until they are reprimanded for not following them. Given the broad nature of the regs, unless it states "training is required", the training won't happen.

PLEASE, support that OHRP require institutions to ensure that initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials. The implementation of such training and education programs WILL help to ensure that individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federalwide Assurances (FWAs) understand and meet their regulatory responsibilities for protecting human subjects.

Thank you,
Lisa Ann Katagiri
IRB Coordinator

Carome, Michael A (HHS/OPHS)

From: Jennifer Phillips [revjphillips@earthlink.net]
Sent: Monday, September 15, 2008 3:58 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training

I am the Chair of the (only) IRB at a state university. I think some regulations pertaining to continuing education for IRB members would be helpful. I feel I am swimming against the current of budgetary constraint in pressing my institution to fund adequate education for new community members and for longer term members especially those helping with expedited reviewing. Currently, only one or maybe two staff people from our research office have funding to attend an annual conference - usually PRIMR/ARENA - this year only one may attend, either the Director of Compliance, or the IRB Chair, or the secretary who handles most of our clerical support, communications, and administration... no IRB members. Whichever of us goes, that person will not be attending the workshops most relevant to the work of the others...so there are huge information gaps on implementation of new regulations, problem solving, and complex emerging issues like electronic research, genetic research, etc. We do some clinical and more social-behavioral-educational research review, so there is a very wide field of knowledge and expertise needed for the IRB, and though we try to do some in-house continuing education it is not nearly enough in depth or breadth for our work. Most recently our Human Research Report subscriptions for members and most staff have been cut as well. Not all our members have computers, and I have none in my office. And this is only part of our resource problems!
Regulations would put some teeth in my and the Director's requests for better educational support. I feel we dishonor our volunteer members by not equipping them adequately for their work. I feel inadequately supported in my own role, though I am studying as best I can on my
own- I am only funded for very part time work and see an increasing volume of protocols for which I carry much responsibility as the main expedited reviewer and determiner of status and pre-reviewer for the IRB.
We use an online CITI training for IRB and researchers which is pretty good, but hardly enough in itself.
Some standards of continuing education would be very helpful.

Sincerely,
Rev. Dr. J.M.Phillips

Carome, Michael A (HHS/OPHS)

From: Peter.Anderson@UCHSC.edu
Sent: Tuesday, September 16, 2008 6:01 PM
To: PSC Humansubjectstraining
Subject: human subjects protection training and education
Attachments: Department of Health and Human Services.doc

Please consider the following comments for the above-mentioned request for information and comments.
Thanks,

Peter L. Anderson, Pharm.D.
Associate Professor
School of Pharmacy
University of Colorado Denver
Box C238
4200 E. 9th Ave.,
Denver, CO 80262
(office) 303-315-1720
(fax) 303-315-1721

Department of Health and Human Services.

Request for information on the implementation of human subjects protection training and education programs.

I would like to comment on some of the questions posed in the above-referenced request for comments. My background on this area is as a principal investigator at the Assistant Professor-level.

1e. Yes, I believe additional guidance and regulation is needed. I believe that regulations must be standardized for all persons involved in all human subjects research, whether the research is institutional-level, OHRP-level, FDA-level, or other. It is confusing to have different regulations for different levels of research. Uniformity is needed. Second, the number of rules (depending on the level of research being conducted) can be difficult to manage and thus some rules might get overlooked. It is also not clear how to document that the rules and regs are being followed. Therefore, it would be extremely beneficial to include PRACTICAL training on how to carry out the day-to-day activities related to human subjects research, and how to document/follow all the rules/regulations in doing so. Perhaps a master checklist could be created that the investigator uses to document that they have been trained for each rule that must be followed in any and all human subjects research. Furthermore, the investigator could complete and submit the same completed checklist each time a new study is implemented and conducted. At the present time, precious little guidance is provided to the investigator on how to organize, document, implement, and self-monitor their research to assure they are following all the necessary rules/regs. The same could be said for IRB members, who also have to keep in mind many rules and regulations. A checklist-based training and system could be mandated to assure that all the rules are followed. Overall, while I believe that such additional training measures will be distasteful to some affected people, I strongly believe that it would dramatically reduce errors and oversights.

2. I think the people who do not focus on becoming expert on rules and regulations need the guidance and training most (e.g. IRB members, principal investigators, co-investigators, coordinators). Usually, such persons are less attuned to the many rules and regs compared with regulatory persons who are thinking about the regs daily.

3a. The training has to cover ALL the responsibilities of the investigator and IRB member (all policies, rules, regs, everything that must be done)! Again, the practical aspects of following (and documenting) the rules/regs is especially needed... the ethical teaching is already sufficient.

3b. The training should include people directly involved in subject contact. It should not be mandated for people more peripherally related to the research (e.g. lab personnel, data-entry people).

3c. Yes, the HIPAA protections and the Belmont report.

3d. The contents should be updated with the changes that affect the requirements of investigators and IRB members in conducting human subjects research.

4. A completed and signed checklist as described in 1e. above.

5. I think people should be required to undergo the full training course if they are involved in the research.

6. Yes, I think periodic training is important. One way to address this without mandating yearly (etc) training is to require a completed checklist (as described in 1e. above) with every study. That would

force the investigator/IRB member to review the rules and regs regularly. Another approach would be automatic emails to investigators when rules change or the IRB adopts new practices.

7. Yes, I think this could be the checklist in 1e.

8. Yes, written or electronic.

Carome, Michael A (HHS/OPHS)

From: Panicker, Sangeeta [spanicker@apa.org]
Sent: Thursday, September 18, 2008 11:43 AM
To: PSC Humansubjectstraining
Cc: Panicker, Sangeeta
Subject: Human Subjects Protection Education and Training
Attachments: OHRP_Comments_HRP_Education_2008.pdf

Dear Dr. Carome:

Attached please find comments from the American Psychological Association (APA) in response to the request for information and comments on the implementation of human subjects protection education and training programs that was published in the Federal Register, Vol. 73, No. 127, Tuesday, July 1, 2008.

Sincerely,

--Sangeeta Panicker

<<OHRP_Comments_HRP_Education_2008.pdf>>

Sangeeta Panicker, PhD | Director, Research Ethics
Science Directorate
American Psychological Association
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Please consider the environment before printing this email.

AMERICAN PSYCHOLOGICAL ASSOCIATION

Science Directorate

September 18, 2008

Michael A. Carome, MD
Captain, US Public Health Service
Office for Human Research Protections
Department of Health and Human Services
1101 Wooton Parkway, Suite 200
Rockville, MD 20852

Re: Request for information and comments on the implementation of human subjects protection education and training programs (Federal Register, Vol. 73, No. 127, Tuesday, July 1, 2008)

Dear Dr. Carome:

The American Psychological Association (APA) appreciates the opportunity to provide the Office for Human Research Protections (OHRP) with comments on the implementation of human subjects protection training and education programs, as requested in the notice published in the *Federal Register*, Volume 73, No. 127, on Tuesday July 1, 2008. APA is the largest scientific and professional organization representing psychology in the United States and is the world's largest association of psychologists. The APA membership includes more than 148,000 researchers, educators, clinicians, consultants, and students. Through its divisions in 54 sub-fields of psychology and affiliations with 60 state, territorial, and Canadian provincial associations, APA works to advance psychology as a science, as a profession, and as a means of promoting human welfare.

APA has long supported and promoted ethical conduct in research with human participants. We stand with OHRP in its firm commitment to the education of identified personnel in the protection of human research participants. As a scientific organization APA values decisions based on empirical research. Thus, the question of whether additional guidance or new regulations for institutional training and education programs on compliance with federal human research protection regulations are required might be answered best by first undertaking a systematic and comprehensive analysis of objective data that are collected by OHRP in the course of its compliance activities, to determine if the underlying cause of

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noncompliance is a lack of education and training or a combination of these and other factors. Such an analysis would allow for a more complete characterization of the nature and extent of noncompliance issues.

Results of the analysis could be used to develop guidance and/or regulation, identify relevant personnel, and also evaluate the impact of the guidance/regulation on future compliance. This analysis could also help OHRP refine or reform the tools and techniques for institutional self-assessments that it offers through its valuable quality improvement program. Finally, the results of the analysis would enable institutions to identify and address underlying causes of noncompliance effectively.

In addition, while OHRP efforts focus on education and training on regulatory compliance, these efforts could be even more successful were OHRP to partner with academic and professional societies to expand educational programs to encompass research ethics more broadly, as recommended by the National Bioethics Advisory Committee (NBAC). In this spirit of cooperation, APA offers its expertise to enhance research ethics training, especially as it pertains to the behavioral and psychological sciences.

Representatives from APA, including Sangeeta Panicker, PhD, the Director of the APA Research Ethics Office, would be glad to follow up on our comments and suggestions. Please do not hesitate to contact Dr. Panicker (spanicker@apa.org or 202.336.6000), if we can be of further assistance to you.

Sincerely,

Steven Breckler

Steven J. Breckler, PhD
Executive Director
APA Science Directorate

Carome, Michael A (HHS/OPHS)

From: Darrell M. Wilson [dwilson@stanford.edu]
Sent: Thursday, September 18, 2008 11:42 PM
To: PSC Humansubjectstraining
Cc: kathy.mcclelland@stanford.edu; AArvin@stanford.edu
Subject: Department of Health and Human Service Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Program
Attachments: OHRP.Call.CommentsPDF.Training.pdf

Hi

Attached please find Stanford University's response to the subject matter. Our institution's commitments to excellence in human subjects research have encompassed continuous training and providing education programs in this area. We strongly believe no further training guidelines or regulations are required to promote our responsible approach in this area. However, we offer the following comments for your consideration for human research protection programs that might not already have a rigorous training and educational program.

Thanks
Darrell

Darrell M Wilson, MD
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See http://dped.stanford.edu

September 17, 2008

Captain, Office for Human Research Protections
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Rockville, MD 20852

E-Mail humansubjectstraining@hhs.gov

Please accept the following comments in response to the Department of Health and Human Services July 1, 2008 Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Training.

II. Request for Information and Comments

(a) Whether OHRP should issue additional guidance recommending that institutions engaged in human subjects research conducted or supported by HHS implement training and education programs for certain individuals involved in the conduct, review, or oversight of human subjects research, or (b) whether HHS should develop a regulation requiring the implementation of such training and education programs.

Comments: We support OHRP issuing additional guidance recommending implementation of training and education programs for individuals who are involved in the conduct, review or oversight of human subjects research. We believe this approach will provide flexibility to organizations to tailor their training and education programs according to varying sizes and natures of their research portfolios. In addition such flexibility fosters innovation in the creation and implementation of locally effective training and education programs.

(1a) Have institutions holding OHRP approved FWAs routinely implemented OHRP's recommendations?

Comments: Yes. In many instances, OHRP recommendations were implemented in our institution. Some examples include short form consent forms, human subjects determination, UPs.

(1b) What, if any, are the reasons for institutions not implementing OHRP's recommendations?

Comments: Some guidance recommendations are overly complicated and difficult to fully understand.

(1c) Has any failure of institutions to implement OHRP's recommendations been a significant contributing factor to noncompliance with the requirements of 45 CFR part 46 and inadequate protection of the rights and welfare of human subjects?