Carome, Michael A (HHS/OPHS)

From: Susan Krivacic [susan@pbgconsulting.com]
Sent: Tuesday, July 01, 2008 12:38 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Traing and Education

RE: Human Subjects Protection-Training and Education

To Whom It May Concern,

As someone who has been on the Board of IRBs over the years and who, from time-to-time serves as a resource for IRBs in terms of protocol review and informed consent review of oncology studies, I do think it is imperative that the FDA develop guidance for organizations involved in human subject protection as it relates to training and education. Since more and more oncology studies are entering the clinical trial pipeline, IRBs and investigators, that previously had no experience in human subject protection of complicated studies and complex diseases like cancer, need to be able to adequately represent and protect subjects contemplating entering these trials. I do think it is imperative that the FDA set some guidelines with regard to training and education of human subject protection, especially as it relates to some of the more complex, chronic, and debiliating disease like cancer, MS, AIDS, etc. Perhaps some of the training and education could focus on disease specific issues. Also, the issue of tissue banking needs to be addressed as well. Many of the IRBs being used today in oncology are commercial, centralized IRBs that are known for getting quick turnaround, but sometimes that can be at a price to the patient. These companies need to have educated and trained staff that understand what to look for in terms of a informed consent document. More needs to be done to meet this unmet need for subject protection, especially in light of the types of trials being conducted today.

Susan Krivacic, Principal
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Carome, Michael A (HHS/OPHS)

From: Lesley Langa [LLanga@IMLS.GOV]
Sent: Wednesday, July 02, 2008 10:49 AM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

Additional guidance to universities or institutions, and/or training for these agents of human-subject research, is necessary. Even though NIH has developed a free online training module for human-subject researchers, and I am currently enrolled in it as a government employee, some researchers are not properly trained in conducted this type of research. Our agency is considering requiring the NIH module for research grantees, and I believe that this will help them produce materials (such as consent forms) for the OMB clearance purposes or for our agency that fulfill the ethical and moral requirements of their research.

In addition, OMB desk officers are reliant on IRBs to properly review and clear research studies for human-subject research, especially when sensitive populations are included in the study. If in fact IRBs are not properly trained, with regard to the regulations on human-subject research, there is not guarantee that the study has rigorously outlined or considered all of the implications of their research population.

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Carome, Michael A (HHS/OPHS)

From: Spike, Jeffrey [jeffrey.spike@med.fsu.edu]
Sent: Wednesday, July 02, 2008 2:20 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

I will try to answer as many of these questions as I can, and as honestly as possible. I have he

I will organize my answers in the order of the questions you provided.

Jeffrey Spike, PhD
FSU College of Medicine
Tallahassee, Florida

(1) In my experience institutions fear regulatory agencies enough to honestly try to fulfill
(1a) Often the problem is that once ethical goals are translated into regulations by lawyers
(1b) About 75% is inertia, it is easier to continue doing what you already know how to do. T
(1c) I don't know any examples that you don't already know. But they occur with regularity,
(1d) Yes, there needs to be promulgation of more specific content. I don't understand the di
(1e) The goal of OHRP, which I share, ought to be to improve the ethics of human subjects res

(This is also the place where I would add that undergraduate education should be encouraged to be

(2) It is essential that any changes made should apply to everyone involved in the research enter

That said, the worst failures I have seen are when senior people are asked to teach the content,

This raises the important question not addresses in your list of questions, who should teach this

How much time should be 'sacrificed' for a good education?
I think the resistance now is whether to allow it to go above 2 hours total, or at some places 14

(3) (3a) No. All the material should be covered for everybody. No one should be on a different

Further observations on teaching ethics: reading a few principles will not evoke any change in b
(3b) No
(3c) Yes. This is not rocket science, this is ethics. IRB members cannot all be expected to
(3d) I don't think the content changes substantially very often. The pace of change in ethic

(4) Yes. This would be revolutionary, and would put scientists more in line with doctors. W

(5) Yes. See conclusions to (2) above. A minimum would be 28 hours of course time, such as

(6) Repeating this too often, when there are few changes will build resentment. I'd be cauti

(7) Yes. But don't let this become the paperwork that distracts people from the pint of the

(8) Yes, with the same proviso as in (7).

(9) I estimate that offering vastly improved training, including the cost of well prepared te

Thanks for this opportunity to share some of my observations from my nearly two decades of experi

Cordially,

Jeffrey Spike

I will try to answer as many of these questions as I can, and as honestly as possible. I have helped to design and teach research ethics courses since 1989 at a number of institutions, and have published on some of the topics. I do wish to make clear that my answers are based on almost 20 years of observations at many institutions, and do not primarily reflect on Florida State's program (which I think is better than most, though I am certainly biased in my judgment).

I will organize my answers in the order of the questions you provided.

Jeffrey Spike, PhD
FSU College of Medicine
Tallahassee, Florida

(1) In my experience institutions fear regulatory agencies enough to honestly try to fulfill all of the minimum requirements put forth in regulations. However mere regulations cannot change behavior, unless accomplished with very severe punishments. The government workers who write regs need to be more educated in social psychology, and understand that they are addressing thousands of people who work together and have shared deeply ingrained habits and values which may need to be changed.

(1a) Often the problem is that once ethical goals are translated into regulations by lawyers and government bureaucrats, only the letter of the law remains, and the spirit is lost. Thus it is very easy for IRBs and other administrators to see themselves as fulfilling the regs without accomplishing any changes in behavior. Commonly, only the consent forms are scrutinized and small wording changes recommended.

(1b) About 75% is inertia, it is easier to continue doing what you already know how to do. The powerful forces of social psychology reinforce this inertia, and the spirit of the regs will lose every time. The other 25% is denial that anything you have always done in the past could possibly have been unethical (especially when you know your motives were good). This will show itself in resentment at the review process, or even disdain or anger. (I try to avoid this reaction by saying that what was done was not unethical at the time, but standards have changed.)

(1c) I don't know any examples that you don't already know. But they occur with regularity, and the cases that are 'caught' are only a small part of the total.

(1d) Yes, there needs to be promulgation of more specific content. I don't understand the difference between "a regulation" and "additional guidance" but current training and education programs are woefully inadequate, far less than merely substandard. Most IRBs and universities see the least intrusive method to get across the least restrictive content. Their goal is to continue getting research dollars, and if following the regs is necessary to do that, they will. (Their goal, in contrast, ought to be to improve the ethical standards of their research. But this is seen as potentially impeding research dollars.) Thus I have seen many (perhaps most) programs satisfied with an online program, some of which can be completed in an hour or two, and none of which can demonstrate any real understanding of the 'big picture' of ethical values for research. All that is required to read a few paragraphs and then parrot back the words on a multiple choice quiz. As a Professor at a medical school, I can tell you this is a shameful failure to take the material seriously, and one which would NEVER be acceptable for the teaching of clinical ethics to future doctors.

(1e) The goal of OHRP, which I share, ought to be to improve the ethics of human subjects research, not just to follow the regulations. We need a way to infuse the spirit of the law, and not just the letter of the law. And we need a way to encourage researchers to aspire to make changes, rather than resist them. This is why training and regulation need to be thoroughly re-examined and strengthened. Another reason why this is a difficult challenge that cannot be met by seeking minimal changes to the status quo is that the research community in the U.S. is not primarily made up of U.S. born citizens. We achieve our scientific greatness by drawing on scientists from China, India, Japan, Taiwan, Pakistan, and many other countries. Those people know the same science as we do, but they were raised with very different values. If we are to have one value system governing our research, we cannot assume the foundations are already in place, we must inculcate it.

(This is also the place where I would add that undergraduate education should be encouraged to be more interdisciplinary, with more required courses in history, ethics, and philosophy. The 'two cultures' view must be avoided, so that scientists can comfort themselves with the view that what they do is objective and value-free. But we can have a only little influence on undergraduate education in the U.S., and we can have even less on undergraduate education abroad. So this is not the answer.)

(2) It is essential that any changes made should apply to everyone involved in the research enterprise, including (but not limited to) 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. This is because of the nature of group psychology; most programs not are ineffectual in part because of their virtually content-less material, but also because it is often only required for those on the bottom of the totem pole (e.g. first year grad students but not post-docs or junior faculty, and certainly not for senior faculty). Seeing the senior people in the room will make the junior people think it is important; and the occasional voice of support from a senior person will imbue the content with importance.

That said, the worst failures I have seen are when senior people are asked to teach the content, even though they don't know the content. This is a frequent occurrence. Then the implicit message is that success in getting grants is more important than knowing anything about research ethics. Or, as one senior person put it: ""Good science is ethical science." Not true, one must be equally concerned about good research methods (such as statistics) AND ethical research methods (e.g. honest and full disclosure of risks to research participants in terms they can understand).

This raises the important question not addresses in your list of questions, who should teach this material? The success of any new regs will depend on how you answer this question. To use an analogy from clinical ethics, it has been said that "Taking legal advice from a doctor is like taking medical advice from a lawyer." Similarly, taking ethical advice from a successful researcher can be like taking scientific advice from a philosopher. My conclusion: science education needs to follow in the footsteps of medical education, and stop thinking they know all the answers important to their field better than 'outsiders.' They need to recognize the value of taking courses outside their own field, and stop seeing it as time taken away from the lab.

How much time should be 'sacrificed' for a good education?
I think the resistance now is whether to allow it to go above 2 hours total, or at some places 14 hours. But even 14 hours is the equivalent of a one credit course. If being a well educated scientist includes mastering this knowledge, then it is worth devoting more time than that to it. Especially given the international group of people involved, this time will potentially influence research behavior around the world. And, in the big picture, that is one those important and valuable things beyond the minimal necessary to satisfy the regs.

(3) (3a) No. All the material should be covered for everybody. No one should be on a different page, since group psychology is one of the things we need to influence. I will add, as an ethicist, that you mention "relevant ethical principles cited in the institution's FWA" but this needs to be fleshed out considerably. One can mention the names of (say) the three principles from The Belmont Report, and not fully develop just what implications they carry. This is how one eviscerates the meaning of having a principled approach. Each principle is an ideal which is hard to live up to, and deserves time for everyone in the group to consider examples (preferably from their own experience) where living up to one of the principles would have required doing something differently.

Further observations on teaching ethics: reading a few principles will not evoke any change in behavior. Small group discussions help more, as do reflective writing, reading essays and personal narratives by scientists, and some history. This type of instruction will be enriching to those with narrow technical educations, will help everyone develop shared values, and is more likely to open minds to the reasonableness and value of changing their behavior.

(3b) No

(3c) Yes. This is not rocket science, this is ethics. IRB members cannot all be expected to be able to define the scientific strength of a proposal, but they should all be able to reflect on whether it is ethical, or whether it treats those issues as minor inconveniences.

(3d) I don't think the content changes substantially very often. The pace of change in ethics is often generational, i.e. major change takes at least a decade or two to evolve and be debated and accepted. I would rather have one or two solid and substantial courses early in a career than a meaningless two hour online requirement that must be mindlessly repeated every year and appears to be a mere nuisance.

(4) Yes. This would be revolutionary, and would put scientists more in line with doctors. We teach clinical ethics and professional integrity throughout the curriculum, and include exam questions on every exam, as well as include its evaluation in narratives that reflect the student's skills and attitudes. (Yes, medical students are graded on their attitude as well as their knowledge.) To transform American science there should be a required course on Research ethics and professional integrity, and ethics questions included in science exams as well. The Research ethics class might even include some of the educational innovations now common in medical education, such as use of Standardized patients and problem based learning and team based learning. (This would involve teaching students using case studies in small groups, rather than lectures, and then testing them by training actors to play the role of research subjects, and having the students try to enroll them in a study protocol.)

(5) Yes. See conclusions to (2) above. A minimum would be 28 hours of course time, such as a one credit course for two semesters, or its equivalent (a two credit course over one semester, or seven four hour half-day sessions).

(6) Repeating this too often, when there are few changes will build resentment. I'd be cautious about this. When I hear this, I think it sounds like a 2 hour refresher course, and there's nothing to indicate the original course was any different from the refresher. But a two hour course is totally inadequate. I would suggest perhaps a refresher course every five years for faculty, to be timed closer to changes in faculty rank. (Perhaps the year after a promotion, so as not to interfere with all the paperwork involved in the promotion process? And to encourage them to consider the promotion as an opportunity to review what hey have done in the past and how they might improve?)

(7) Yes. But don't let this become the paperwork that distracts people from the pint of the exercise, which is not preparing evidence of training, but to improve training.

(8) Yes, with the same proviso as in (7).

(9) I estimate that offering vastly improved training, including the cost of well prepared teachers (such as PhDs in bioethics who have taught this material before in research universities) and the use of some Standardized Patients (SPs) would come to 1%-2% of total grant costs. The higher estimate (2%) includes costs to improve IRB functions, such as developing regional IRBs to avoid the inevitable conflicts of interest from individual institutional IRBs, additional staff, and even some reimbursement for travel time for people to use pooled resources (e.g. a classroom at a nearby university for people from three to six different IRBs). I have included this cost estimate in an article of mine as well: "Putting the 'Ethics' into 'Research Ethics," *American Journal of Bioethics*, 5:1, 51-53 (2005).

Thanks for this opportunity to share some of my observations from my nearly two decades of experience in the field.

Cordially,

Jeffrey Spike

Carome, Michael A (HHS/OPHS)

From: Satish Kalhan [sck@case.edu]
Sent: Thursday, July 03, 2008 1:19 PM
To: PSC Humansubjectstraining
Subject: Human Subject protection Training

Although the efforts of OHRP are laudatory and much has been accomplished by implementation of various efforts. What has been missing is the evaluation of these efforts and the impact they have had on conduct of human Research and the burden they has placed on the investigators. Additional education and training without evaluating the impact of the past is not likely to be fruitful.

If the goal is the protection of human subjects, then effort should be made to examine whether all these mandates have actually improved or protected human subjects.

All these requirements have done are 1) created long and not easy to understand consent forms; some as long as 20 pages. I doubt whether the investigator or the participating subject know the contents of these consent forms.
2) Converted IRBs into a local policing unit; who spend a lot of time enforcing their own interpretation of the rules, auditing investigators and essentially stifling research.
3) additional bunch of not easy to understand HIPPA forms.

What is immediately required is a reform of the IRBs; especially what should be the qualifications and training of the members of the IRB, its administrators and what rules they should follow in implementing the so called "requirements", regulations and most importantly what is the optimal way of ensuring ethical conduct of human research and protection of participants.

My impression at three different institutions is that IRBs are run by individuals who themselves have no experience in human research, are mostly bureaucratic, rule enforcers who are doing their (
involuntary) best to stifle outstanding research. At this juncture their education and training is critical .

Therefore, there is an immediate need for Federal requirements to help ensure that the IRB members and more important the administrators (and not the investigators),be adequately educated and sensitized to human subject protection. Their education and training should not be just theoretical review of the past ie Tuskegee study and Belmont report. They should all be required to participate (observe, documented by the time spent) in the actual conduct of human research with the investigators; this should include preparing the research protocol, the consent process and the actual implementation of the research protocol including the conduct of the study. (The institutions should be required to compensate the members of the IRB for their effort) Only then we shall be able to not only continue ethical conduct of human research but also ensure that outstanding research is not suppressed and is actually fostered in the USA.

Thus the proposed effort although very important should be entirely focused on IRBs, their administrators and members and not the investigators. The later are already burdened by the many regulations and requirements associated with the research, have to work hard to obtain grant support, and to conduct the research. Additionally the impact of previously implemented requirements on the overall human subject protection should be evaluated.

Satish Kalhan MD

Satish C Kalhan MD

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Carome, Michael A (HHS/OPHS)

From: Joan Buddecke [buddeckj@kernmedctr.com]
Sent: Thursday, July 03, 2008 1:58 PM
To: PSC Humansubjectstraining
Subject: http://www.hhs.gov/ohrp/documents/fedreg20080701.htm

Yes, I am supporting required initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials.

However, in this era of severe budget constraints on publicly owned academic medical centers and teaching hospitals, I STRONGLY URGE THAT OHRP HAVE THE REQUIRED INITIAL AND CONTINUED EDUCATIONAL TRAINING AVAILABLE ON-LINE FOR ALL PARTIES TO ACCESS AND COMPLETE TO MEET ANY EDUCATIONAL REQUIREMENTS INSTITUTED BY OHRP.

Respectfully submitted,

Joan K. Buddecke, M.S., R.N., C.I.M.
Institutional Review Board
Kern Medical Center
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Bakersfield, CA 93305

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Carome, Michael A (HHS/OPHS)

From: Orem, Laura [Laura.Orem@FLHOSP.ORG]
Sent: Thursday, July 03, 2008 2:31 PM
To: PSC Humansubjectstraining
Subject: "Human Subjects Protection Training and Education"

Training should be mandatory to put authority and respect behind it.

Laura Orem, CIP, CIM
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(407) 303-5581
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laura.orem@flhosp.org

Florida Hospital Institutional Review Board - Protecting Volunteers in Research

Carome, Michael A (HHS/OPHS)

From: Joel MacAuslan [JoelM@STARAnalyticalServices.com]
Sent: Thursday, July 03, 2008 2:44 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

It is reasonable to require that all NIH-supported institutions require that their personnel obtain training, if those personnel are involved in aspects of human subjects research that require IRB approval.

But do ***NOT*** require that those institutions implement such training themselves! (We are a three-person company!)

-Joel MacAuslan
President & Chief Scientist

--
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http://www.STARAnalyticalServices.com

Carome, Michael A (HHS/OPHS)

From: Schaffer, Dana [schaffer.de@ghc.org]
Sent: Thursday, July 03, 2008 2:48 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

To Whom it May Concern:
Option b states:
HHS should develop a regulation requiring the implementation of such training and education programs [for certain individuals involved in the conduct, review, or oversight of human subjects research].

My opinion is that OHRP should develop a regulations that require the training of only IRB members and the Institutional Official, and **only if OHRP develops the online training course materials**. One of the new regulations, could be that at least one member of the IRB should be a compliance/regulatory specialist.

I do not think that OHRP should indirectly encourage institutions to join a private entity/certification organization PRIM&R/AHRQ, just so the institutions won't have to put man-power into developing a training course and hire people to implement the training course. OHRP should provide the training course or not require it at all. It is nice that people are getting CIP certifications; however, small IRBs/institutions do not have the budget to pay for all their IRB members and staff to be members and get certified through these private organizations.

There is a trend toward the government "outsourcing" regulatory oversight and development of standards to private organizations like PRIM&R/AHRQ. While this makes less work for the governmental regulatory bodies, it means ever increasing burden on institutions. This is because it is in the best interests of the private organizations to require an ever increasing number of standards, which can only be met and accessed by joining the private organization, and which translate into increased fees to keep the private organizations perpetuating more standards, hiring more people, and growing a pyramid scheme. In order to get a job many institutions require CIP certification already - so that individuals will come groomed to conform to AHRQs standards - not to the federal regulations. This puts pressure on organizations to join. What should be required, is a sound background and demonstrated ability to understand and apply the federal regulations. However, since the regulations and guidance have fallen behind, sound background in understanding an applying federal regulations is not enough to get one a job applying those same regulations.

Instead, OHRP should provide more guidance on standard practices and training materials.

Sincerely,

Dana Schaffer
Research Review Analyst
Human Subjects Office, Center for Health Studies, Group Health Cooperative
1730 Minor Avenue, Suite 1600 Seattle, WA 98101
schaffer.de@ghc.org

Carome, Michael A (HHS/OPHS)

From: Ernevad, Eva [EvaErnevad@Centura.Org]
Sent: Thursday, July 03, 2008 4:01 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

Good Afternoon,

I vote for: (b) HHS should develop a regulation requiring the implementation of such training and education programs.

It will capture more people that need to be trained properly and review for those that already are trained properly.

Best Regard,
Eva

Eva Ernevad
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Carome, Michael A (HHS/OPHS)

From: Marguarette M. Bolton [mmb1@nyu.edu]
Sent: Thursday, July 03, 2008 6:23 PM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

I feel that, outside of the required CITI or other human subjects tutorials/exams, and PRIM&R conferences, there is no other educational or training programs offered to IRB staff/administrators, committee members and investigators. These training and educational programs should cover Social, Behavioral and Educational Research along with Biomedical Research for all participants, so that everyone gets a complete picture of human subjects protection and its regulations. These training and educational sessions could be web broadcasted, similar to those that Grants.gov offered when the NIH was moving over to electronic submissions. These types of sessions would enable OHRP to reach a broader number of participants, and more people could take part in these sessions if their organization has budgetary or time constraints.

Should OHRP mandate these educational and training programs? I am not sure. On one hand, (a) it would enable individuals to take part in these programs when their institution will not allow them the time or money to participate; or (b) newcomers to the IRB (staff/administrators, committee members and investigators) be mandated to participate in at least two sessions given how the curriculum is set. On the other hand, do we need another mandate? Another thought would be to offer an incentive for individuals who participate in these programs such as receiving CEUs toward their certification or re-certification.

I believe there is a definite void in regular training and educational programs for not only IRB staff and administrators, but also committee members and investigators. Implementing such training and educational programs to IRB individuals and investigators will assure them, and OHRP, that a better understanding of the regulatory responsibilities for protecting human subjects will be accomplished.

Marguarette M. Bolton
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Carome, Michael A (HHS/OPHS)

From: Lisa Marsh [lisaymarsh@gmail.com]
Sent: Friday, July 04, 2008 12:43 PM
To: PSC Humansubjectstraining

I believe this should be regulated by federal requirements. From my experience a minority of academic institutions are adequately mandating Human Subjects Protection training while a majority have failed. Private research by physicians in private practice that utilize central IRB's are not routinely required to have training and if the IRB does require it they aren't verifying the training by having PI's submit documentation as to such. I have worked with several Principal Investigators that have not had formal training in Human Subjects Protection and this is a detriment to all involved in Human Subjects Research.

Sincerely,
Lisa Marsh RN, BSN

Carome, Michael A (HHS/OPHS)

From: Gloria_Duke@uttyler.edu
Sent: Friday, July 04, 2008 3:40 PM
To: PSC Humansubjectstraining
Subject: human subjects training request for info

As Chair of our IRB for the past 4 years, I am in favor of the HHS mandated education. I am fortunate enough to be at an institution that provides resources for this even though it is only an FWA recommendation, and we are concerned enough about the adequacy of human subjects protection that we do mandate education for our PIs and co-investigators, and make them responsible for ensuring the education and training of other related persons (e.g., research assistants). We developed our own on-line system that was tailored to HHS regulations about human subjects as well as institutional-related information. If you need any further information, please do not hesitate to contact me.

Gloria Duke

Gloria J. Duke, PhD, RN
Associate Dean, Office of Nursing Research & Scholarship
The University of Texas at Tyler
College of Nursing & Health Sciences
3900 University Blvd.
Tyler, TX 75799

903-566-7023

Carome, Michael A (HHS/OPHS)

From: Harry McGee [mcgeeh@michigan.gov]
Sent: Monday, July 07, 2008 7:47 AM
To: PSC Humansubjectstraining
Subject: "Human Subjects Protection Training and Education"

HHS should develop a regulation requiring the implementation of training and education programs. It would make the most sense for OHRP to offer online training. This would assure that training standards are adequate and uniform. It would also be the most efficient way.

Harry McGee, MPH
Health Policy, Regulations & Professions Administration Institutional Review Board
517-241-0806
7th Floor Capitol View
201 Townsend
Lansing, MI 48913

"If we knew what we were doing it wouldn't be research." Albert Einstein

Carome, Michael A (HHS/OPHS)

From: Williams, Nancy [nwilliams@maryville.edu]
Sent: Monday, July 07, 2008 10:01 AM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

1. The training and education of researchers, institutional representatives, and IRB members should be required.

2. Support for and certification of such training should be provided via on-line vehicles offered or supported by HHS.

   I say this because (1) there needs to be reliability in the training....I'd prefer training from HHS which would be consistent across institutions and accurate....and (2) because those of us in small institutions who are attempting to meet the guidelines, even though we may not even have federal grants, etc....do not have the people or monetary resources to construct or maintain our own training or education modules or on-line sites...

I'm not certain this answers the question forwarded...but hopefully it does!

Nancy Williams, Ph.D.
Assistant Dean, School of Education
(Chair, Maryville University IRB)

Carome, Michael A (HHS/OPHS)

From: Roy, Micki [Micki.Roy@STJUDE.ORG]
Sent: Monday, July 07, 2008 10:05 AM
To: PSC Humansubjectstraining
Subject: "Human Subjects Protection Training and Education"

I think the OHRP must require training and education for anyone engaged in human subjects research no matter who supports or funds the research.

Micki Roy, BS, CCRC
Coordinator, Clinical Research
Billing and Cost Analysis
Office of Research Billing Compliance
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332 N. Lauderdale, Mailstop 720
Memphis, TN 38105
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-----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 12:48 PM
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: Dr. Sandy Hunter [sandy.hunter@eku.edu]
Sent: Monday, July 07, 2008 10:53 AM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

Per your agency's request for written comments, please accept the following:

As an IRB member and researcher, I applaud OHRP's efforts to further ensure the safety of human subjects. To that end, I support the establishment of additional guidelines for on-going (validated) training for IRB members. I strongly suggest that this training be available in multiple formats (e.g., internet, CD, hardcopy) and that some testing rubric be developed along with it.

Dr. Sandy Hunter, NREMT-P
Professor
Paramedic Program
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Eastern Kentucky University
521 Lancaster Avenue
Richmond, KY 40475
859-622-1028

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Carome, Michael A (HHS/OPHS)

From: Jack Fuqua [jfuqua@FairwayMed.com]
Sent: Monday, July 07, 2008 11:04 AM
To: PSC Humansubjectstraining
Subject: IRB member education

I believe that OHRP should require institutions to ensure that both initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials. In some instances IRB members serve for decades without any continuing education.

Jack Fuqua
Manager of Clinical Affairs
Fairway Medical Technologies, Inc.
P: 713-772-7867 F: 713-772-2010
jfuqua@fairwaymed.com

Carome, Michael A (HHS/OPHS)

From: Sharon Hiemenz [cccf_trials@hotmail.com]
Sent: Monday, July 07, 2008 11:06 AM
To: PSC Humansubjectstraining
Subject: Human Subjects Protection Training and Education

I have been a research coordinator for over 20 years at university and private practice study sites.

I have the following recommendations:

Training in Human Research Protection should be required for all IRB members and IRB administrative staff, all Investigators listed on the 1572, and research coordinators involved in the consenting process. Training in Human Research Protection should be recommended for all study personnel involved in educating subjects about clinical trials, or otherwise involved in the conduct of the trial.

Concern: When training is mandatory minimal standards for the training must be specified, and training should be available at no cost and in an easily accessible format, and the information about free training and certification readily available. Excellent Training in Human Research Protection is currently available through Clinical Trials Networks Best Practices: NIH Roadmap (https://www.ctnbestpractices.org/edu/cmeceu/humanprotect), and the NIH. Some institutions over interpret regulations, therefore "continuing education" should have a more specific definition such as: annual education on changes in the recommendations or regulations pertaining to Human Research Protection, and recertification every 5 years.

Thank you for inviting comments.

Sharon

Sharon Hiemenz, RN, BSN, CCRP
Director Clinical Trials Office
Cancer Centers of Central Florida
9832 US Highway 441, Suite 101
Leesburg, FL 34788

Phone: (352)787-3341
FAX: (352)787-0178
E-mail: CCCF_Trials@hotmail.com

Subject: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs
Date: Thu, 3 Jul 2008 15:19:10 -0400
From: Michael.Leon@FLHOSP.ORG
To:

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

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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.

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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: Azerbaijan Medical Association [azerma@hotmail.com]
Sent: Monday, July 07, 2008 11:35 AM
To: PSC Humansubjectstraining
Cc: lee_helen@bah.com
Subject: "Human Subjects Protection Training and Education"

To:Michael A. Carome, M.D.
Captain, U.S. Public Health Service, OHRP

Dear Michael,

I have recievied an email from Sina Barbara (Fogarty /NIH) (email to Sina Barbara was sent from Helen Lee), where have information about possibility of implementation of Human Subjects Protection Training and Education Programs.

As Azerbaijan Medical Association we are very interested in organization of such trainings and education programs for our physician -researchers . If your organization could help us within organization of such trainings and education programs we would be very greatful.

Please , write us how we could cooperate witgh your organization regarding above mentioned important mission.

We hope our beneficial cooperation will be establish and progress.

Best regards,

Nariman N. Safarli, M.D.
President
Azerbaijan Medical Association(AzMA)

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