September 28, 2008

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Office for Human Research Protection
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Rockville, MD   20852

RE: Request for Information and Comments on the Implementation of Human Subjects Training and Education Programs (Federal Register Notice dated July 1, 2008)

Dear Dr. Carome,

Thank you for offering entities and organizations the opportunity to provide comment on this notice. We applaud OHRP for its efforts in seeking information regarding relevant and appropriate mechanisms for enhancing protection of human subjects through education training programs for IRB members and staff, investigators and certain institutional officials.

We appreciate that several federal institutes, commissions and advisory committees have made recommendations regarding enhanced human subject protection training requirements for the past 10 years. The proposed strengthening of the human subject protections training requirement has many advantages if such implementation provides the flexibility for institutions to develop performance based programs in much the same way that is defined in the Laboratory Animal Welfare regulations. General guidance on topics and frequency of training could be very constructive and useful for institutions and entities in upholding their Federal Wide Assurances and compliance with the terms of the assurances’ training and education program for protecting human subjects.

This Notice and request for comments provides a forward thinking opportunity for OHRP. It is our hope that the experience gained by the Collaborative Institutional Training Initiative (CITI) will offer data, perspective and insight to this process.

The comments that follow have been developed by the Executive Advisory Committee of the Collaborative Institutional Training Initiative (CITI).
Introductory CITI comments:

The Collaborative Institutional Training Initiative (CITI) Program is an international web-based research ethics education program, designed to meet the June 2000 NIH mandate for training in protection of human subjects. The Program has had considerable experience, during the past 8 years, in the development, distribution and implementation of web-based educational programs for training in the responsible conduct of research including “The Protection of Human Research Subjects” and “Good Clinical Practice” (GCP). The CITI Program, founded by Karen Hansen and Paul Braunschweiger Ph.D., opened its first course on September 1, 2000 to 10 collaborating institutions in the U.S. As of 9-1-08, 947 institutions and organizations around the world use the CITI Program. These participants include universities, small colleges, community colleges, community hospitals, major medical centers, research institutes, Federal Departments (e.g., Department of Veteran’s Affairs, Department of Navy, and Department of Energy), Federal agencies, industry and other entities engaged in human subjects research. Currently, more than 22,000 people complete a course at www.citiprogram.org each month. Since September 2000, more than one million investigators, staff and students have completed a CITI Course.

The CITI Program is administered from the Office of Research Education and Training at the University of Miami, Miami, Florida. The co-founders are aided by the CITI Developers Group and the CITI Executive Advisory Committee, chaired by Dr. Ernest Prentice, University Nebraska Medical Center.

The CITI Program offers Basic and Refresher courses in Human Subjects Protections, “Good Clinical Practice” and Health Information Privacy and Security (HIPS). Due to demand, courses are currently available in English, Spanish, and Portuguese. The Program is used in more than 34 countries and CITI is developing partnerships to provide course content in Chinese, Japanese, French and Georgian. In addition to the Human Research Subjects courses, the CITI Program also offers courses in the Responsible Conduct of Research and Laboratory Animal Welfare.

Attendant with each course is the opportunity for each learner to submit responses to an anonymous, IRB-approved, learner satisfaction survey. These surveys completed at the end of the course, provide the CITI Developers with feedback about the program, suggestions for improvement, opinions about human subjects training in general and web-based programs in specific. Aggregate demographic information and information obtained from the satisfaction surveys provide the basis for the response to many of the issues raised by this Request For Information (RFI).

CITI Response to Individual Questions:

(1a) Have institutions holding OHRP-approved FWAs routinely implemented OHRP’s recommendations?
CITI Response:

A large number of institutions and organizations around the world have adopted the CITI Program as a component of their human subjects research training program. As of September 2008, over 947 sites use the CITI program to meet the June 2000 policy training mandate. More than 1 million people have completed a CITI Course and currently that number is growing at the rate of approximately 23,000 new learners per month. This new learner enrollment rate has been increasing steadily over the past 8 years.

It would appear that now 8 years after Dr. Shalala, then Director of the Department of Health and Human Services, announced the June 2000 educational policy, institutions conducting human subjects research are meeting the spirit if not the letter of the policy. It is, however, very likely that there still may be sites where training in the protection of human subjects is still not optimal. In partial support of this hypothesis is the fact that institutional enrollment in the CITI program has markedly increased during the past year. Currently, the CITI Program is adding approximately 20 new institutional participating sites each month. We believe that AAHRPP accreditation may be driving some of this growth, as organizations move to upgrade their education programs.

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

CITI Response:

Possession of an OHRP-approved Federal Wide Assurance (FWA) would require compliance with OHRP recommendations. The most obvious reason for not implementing OHRP recommendations is that an organization does not have an FWA or is not conducting Public Health Service (PHS)-funded research. To this point, more than 65% of all human subjects research projects are industry-sponsored trials conducted in the community, without PHS funding and thus, beyond the oversight of OHRP. The FDA, which does regulate many of the industry-sponsored trials, has a requirement for IRB review, but no specific regulatory requirement for training in the protection of human research subjects.

It seems inconceivable that institutions and organizations with an OHRP-approved FWA would knowingly disregard the June 2000 mandate for investigator training in human research subjects protections. There does seem, however, to be an increasing awareness in the research community that students (undergraduate and graduate) responsible for human subjects research projects should also be included in the education mandate. Growth of the CITI Program and data from user satisfaction surveys supports this idea. Further, the demographics of the organizations joining the program during the past 9 months would suggest that small colleges, community hospitals and industry are realizing
that they should also provide educational programs on the ethical issues fundamental to the conduct of human subjects research and the regulations designed to require investigators to document that their research is conducted to the highest ethical standards.

As an example, data collected September 1, 2008 indicated 113 new organizations have joined the CITI Program since January 1, 2008. Rather than major universities and medical centers we have detected a shift in the type of organization joining the program. This likely reflects some new trends in federal funding, but, also an increasing awareness of the need for high quality training programs to protect human subjects. Since January 1, 2008 the newly enrolled institutions sorted out as follows:

- 32% corporations conducting biomedical and survey research
- 29% colleges and small (<12,000 students) universities
- 20% community hospitals and medical centers
- 12% major universities
- 7% other (e.g., government agencies)

This demographic shift suggests the recognition by many corporate entities and small liberal arts colleges and universities that they too should provide training for their faculty, staff and students who conduct research with human subjects. Satisfaction survey data suggest that in excess of 27% of all CITI Program enrollments are by individuals who self identify as “students” or fellows.

It is likely that there are many other organizations and small colleges that should be providing research ethics education to their investigators, staff and students conducting social and behavioral research with human subjects.

Further, there are many people participating as subjects in non-PHS funded, industry-sponsored human subjects research in the community who do not have the benefit of investigators, specifically trained in how to adequately protect the subjects from research harms.

(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? If so, please provide examples.

CITI Response:

CITI has no specific knowledge of such occurrences in the U.S. However, learner satisfaction survey data collected in 2005, asked learners to respond to the following:

*Having completed the CITI Course in Human Subjects Protections, I now realize that I have previously observed unethical behavior in the conduct of human subjects research. 1 = strongly disagree 10 = strongly agree.*
Approximately 17% provided a score of 8, 9, 10, indicating a high degree of certainty that they had previously witnessed unethical behavior. (http://www.citiprogram.org/citidocuments/admin/SACHRP1pb.ppt; slide 38)

Thus, the CITI education program permitted some learners to recognize questionable behaviors that otherwise went unquestioned.

There have been many instances internationally where better training of investigators and CRO personnel might have prevented unethical research practices and harms to subjects.

(1d) If failure of institutions to implement OHRP’s recommendations has 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, would promulgation of a regulation requiring institutions to implement training and education programs for certain individuals involved in the conduct, review or oversight of human subjects research be the best mechanism to address this problem, or should different mechanisms be used (for example, would it be better if OHRP instead issued additional guidance regarding training and education programs)?

**CITI Response:**

Given the financial, academic and professional pressures associated with the clinical research enterprise, it is unclear that someone who completes only 4-6 hours of instruction in research ethics will always behave with the highest degree of professionalism. However, it is likely that without rigorous and comprehensive research ethics educational requirements, subjects will be at increased risk from the uninformed or purposefully unethical behavior of investigators.

Clearly, to be effective, the educational mandate must extend to all members of the research team. The CITI Program Satisfaction Survey has addressed this very issue. In 2005 and 2006 we asked survey takers about the need for training in protection of human subjects. In excess of 80% of more than 6000 survey respondents indicated strong agreements with the June 2000 PHS policy requiring human subjects protection training. (See https://www.citiprogram.org/citidocuments/aahrpppbfinal.ppt; slide 3)

Further, in excess of 80% of the survey respondents have felt very strongly that the educational program provided to them by their institution and CITI increased the level of awareness to the ethical issues of human subjects research at their institution. (See https://www.citiprogram.org/citidocuments/aahrpppbfinal.ppt; slide 4).

Finally, when survey subjects were asked specifically about who should receive the training in protection of human subjects, more than 80% of respondents
believed strongly that all members of the research team and not just the investigator should be well grounded in the ethics of human subjects research and the mechanisms by which human subjects are afforded protection from unnecessary research harms.
(See https://www.citiprogram.org/citidocuments/M25_Promoting_integrity.ppt; slide 15.)

**The Elements of Compliance**

When an investigation occurs under the compliance rubric, in addition to the usual procedural steps, federal inspectors often look closely to determine whether the institution has promoted an organizational culture that encourages integrity and compliance. They use the following recommended compliance elements listed in Chapter Eight of the Federal Sentencing Guidelines for Organizations (FSGO) as a guide for making this determination:

1. Implementing written policies and procedures;

2. Designating a compliance officer and compliance committee;

3. **Conducting effective training and education;**

4. Developing effective lines of communication;

5. Conducting internal monitoring and auditing;

6. Responding promptly to detected problems & undertaking corrective action;

7. Enforcing standards through well-publicized disciplinary guidelines.

Institutions that have a proactive compliance and ethics plan in place receive credit on their overall “culpability score.” Kenneth Johnson, in an Ethics Resource Center article, points out that fulfillment of the seven requirements is “the hallmark of an effective program that encourages compliance with the law and ethical conduct.” He points out, however, that the FSGO creators continuously signal “that these ‘seven minimum requirements’ are not so much the ‘elements’ of an effective program as they are ‘indicators’ that due diligence and promotion of the desired culture occurred.”

Thus, the CITI Program recommendation is that the current educational mandate should be continued and strengthened with additional guidance from OHRP. The CITI Program experience is that many institutions and organizations have very rigorous educational programs for their investigators and staff. It is a concern of the CITI Program that new Federal regulation will have the unintended consequence of indicating to institutions that they can meet the letter of the law by reducing their training programs to something that is proscribed by OHRP.
proscribed educational program may also have the unintended consequence of placing a burden on investigators that is unwarranted based on their role in human subject research.

Thus, it is the recommendation of the CITI Program that educational programs for protection of human subjects be required and that such programs should be stratified according to the type of research being conducted (Biomedical and/or Social & Behavioral) and the role (i.e., investigator, student, study coordinator, or lab technician) of the individual. Further, rather than programs that are engineered from federal regulation, the education programs should be institution-driven and be performance-based.

(1e) Even if there are no data suggesting that failure of institutions to implement OHRP’s recommendations regarding education and training has been a contributing factor in noncompliance with the requirements of 45 CFR part 46, are there other sound reasons for developing further guidance or a regulation regarding education and training, and if so, what are they?

CITI Response:

Human subjects research is a privilege and not a right provided by an advanced degree. Most human subjects research is supported in some way through funds provided by public funding. Whether this is from taxpayer dollars, equity investments or private foundation support, the public expects that research with human subjects will be conducted to the highest level of professionalism and integrity. Without integrity and importantly the documentation of integrity that the regulations require, the public trust is put in jeopardy. Without the public trust human subjects research cannot flourish, and new discoveries will not be forthcoming in time to save lives.

Research ethics education including human subjects protection training is the foundation for promoting ethical behavior and integrity in the research enterprise. Further, education extended to the entire research team provides the group or team ethic necessary to help all team members avoid procedural short cuts and conflicts of interest and commitment that could taint the research and the research record.

Data from the CITI Satisfaction Survey indicate that learners feel strongly that the human subjects research courses have provided them the ethical foundation and knowledge base to conduct their research at the highest ethical level and that completing the educational requirement will help them do better science. https://www.citiprogram.org/citidocuments/ADMIN/NAID.ppt

The CITI data also indicates that at least some learners are energized to do more to protect human subjects. For example, when survey participants were asked about their willingness to take a more active role in human subjects protections,
more than 60% of respondents indicated a strong belief that after the course they were in a better position to advise a colleague or student on a human subjects research issue. Further, 34% of respondents indicated a strong intent to join an IRB or a Data Safety Monitoring Board to take a more active role in protecting human subjects. See slide 65, slide 66 at: https://www.citiprogram.org/citidocuments/ADMIN/NAID.ppt;

(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)?

CITI Response:

Data from the CITI Human Subjects Research Course Satisfaction Survey indicate that respondents strongly agree that ALL members of the research team should be required to complete an educational program in the protection of human subjects commensurate with their roles and responsibilities in research. This would include, but not be limited to, investigators, staff, students, post-docs, fellows, clinical research associates, study coordinators, statisticians and people doing research with human data or specimens only.

In addition it is clear that those individuals with institutional oversight responsibilities for human subjects research also should have customized instruction not only in the protection of human research subjects, but also specific training as is appropriate for their role in the research enterprise. These should include:

- The institutional official
- Compliance office personnel
- IRB chairpersons
- IRB members and
- IRB professionals

Institutions that participate in the CITI Program have clearly embraced this approach. Institutions, often with guidance from CITI staff, design specific curricula for different segments of their research community depending on their role in research. For example:

- IRB chairs, IRB members and IRB professionals tend to have the most comprehensive educational requirements that include modules dealing with both biomedical as well as with social and behavioral research issues.
• Investigators conducting studies with investigational biologics, drugs and devices also tend to have a comprehensive curriculum that might include a course in “Good Clinical Practice.”

In addition to “Basic Training” for new investigators, most institutions that participate in the CITI Program also have a “Refresher Course” as part of their continuing education requirement for all individuals covered by the basic course training requirement. Although this is not specifically mandated by the June 2000 Policy, most institutions have adopted a “refresher” or “recertification” requirement. This normally is required at one, two, or three years after the Basic Training requirement has been completed.

It is the CITI Program recommendation that specialized and role appropriate training for all individuals involved in the conduct and oversight of human subjects research be required by the institution. OHRP policy should be strengthened with guidance to clearly delineate the expectation of such training and educational opportunities.

(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, 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)?

CITI Response:

The CITI Program recommends that guidance should include recommendations that institutional human subjects training should be:
• Promoted at institutions from the top down
• Conducted with integrity to promote the Public Trust
• Programmatic in nature and flexible to include multiple learning paradigms
• Designed in a layered fashion to meet the needs of investigators, staff and students according to research discipline, research interests, and role in the research enterprise
• Carefully documented for research sponsors
• Rigorously applied to all members of the research team
• Reinforced at appropriate intervals with continuing education instruction

The knowledge base of the learners should generally be determined, and the educational program should be reviewed regularly for content accuracy and
relevance. For example, The CITI Program course content is reviewed semiannually and changes made as is deemed appropriate by the editorial board.

The CITI Program recommends OHRP develops guidance for a rigorous basic educational program that includes:

1) The *Belmont Report* as the principles apply to all research but are implemented differently given the wide range of disciplines and research methods in a changing research enterprise. Guidance should focus on institutions teaching the *Belmont Report* and how it pertains to and informs the kinds of research taking place at the institution.

2) Specific Biomedical and Social and Behavioral Research content in the following areas:

- History and Ethical Principles
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Defining Research with Human Subjects
- Informed Consent
- Assessing Risk in Social and Behavioral Sciences
- Privacy and Confidentiality
- Social and Behavioral Research for Biomedical Researchers
- Records Based Research
- Genetic Research in Human Populations
- Research With Protected Populations: Vulnerable Subjects: An Overview
- Vulnerable Subjects - Research with Prisoners
- Vulnerable Subjects - Research Involving Minors
- Research in Public Elementary and Secondary Schools
- Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero
- Group Harms: Research With Culturally or Medically Vulnerable Groups
- FDA-Regulated Research
- Internet Research
- International Research
- Human Subjects Research at the VA
- HIPAA and Human Subjects Research
- Workers as Research Subjects: A Vulnerable Population
- Conflicts of Interest in Research Involving Human Subjects
- What Every New IRB Member Needs to Know
- Students in Research

The CITI program permits institutions to choose modules from the list of topics referenced above to build the curriculum for a specific segment of their research community. Depending on the discipline and role of the learner in the research enterprise, courses may be as short as 5 or 6 modules or as long as 23 or 24 modules.
(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?

CITI Response:

The CITI Program recommends that the human subjects research training and education should be tailored to the research discipline, the interests of the investigator and the role of the learner in the research enterprise. This has been a tenet of the program since its inception in September 2000. The program has been designed to give institutions maximal flexibility in designing specific courses to address the needs of their research community members. For example:

- Biomedical and Social and Behavioral Research often have different risks, employ different research procedures, different data collection methods and different methods of data analysis. Training programs that address only issues relevant to the clinical investigator will be rejected as irrelevant by the large segment of the research community conducting social and behavioral research including students at the undergraduate and graduate levels.

- Training must be stratified according to the individual’s role in research. Clearly, investigators conducting human subjects research with investigational drugs and devices should have a higher density of training and education than someone who is conducting studies with human tissue samples or de-identified data only.

- IRB Chairs, IRB Members and IRB professionals require the highest density of training in research ethics, human subjects regulations and IRB procedures. They should also have a clear understanding of what constitutes conflict of interest and commitment and understand the basics of responsible data acquisition and management. Training for this group should take many forms including but, not limited to:
  - Web-based basic training
  - Annual refresher courses, seminars and/or specialty workshops
  - Regular training or case study review as a component of the IRB meeting
  - Attendance at national meetings such as Public Responsibility In Medicine & Research (PRIM&R)
  - Professional certification such as the Certified IRB Professional (CIP) certification
  - Regional workshops offered by OHRP

(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?
CITI Response:

The CITI Program recommends that OHRP should refrain from engineering a specific human subjects research protections curriculum for all HHS-funded investigators. Further, we believe that it is unnecessary for OHRP to set a minimal level of achievement or design a national qualifying exam in order to qualify to conduct human subjects research on HHS-sponsored projects.

We believe that this would be an unnecessary exercise that would likely be politicized and may actually result in a less rigorous approach to human subjects research education than now exists through voluntary compliance and a performance-based approach to institutional training programs. The CITI Program has had much experience over the past several years helping institutions design the basic educational requirements for institutional human subject protection programs. The CITI Program recommends that training requirements, recertification intervals and basic level of proficiency are decisions that are best left to the institution.

Effective programs:
- Incorporate multiple forms of learning including basic text, case studies and specialized workshops
- Exhibit integrity by
  - Documentation of training activities
  - Evaluating their training programs to determine that they are meeting institutional goals
- Reinforce the knowledge base with seminars, workshops, and “refresher” continuing education courses for investigators, staff and students

(3d) How often should the content of the materials used for this training be updated?

CITI Response:

Materials used in training should clearly be updated as frequently as is necessary to incorporate any new regulations or guidance into a specific module in the curriculum. Materials should be reviewed on no less than an annual basis for content and accuracy. CITI participating institutions have the benefit of semi-annual review and update of all CITI content. Such updates are based partly on the review of learner feedback to the program by content experts.

(4) Should further guidance or a regulation include provisions stipulating that proficiency in human subjects protection requirements be demonstrated in some way (please specify)?
CITI Response:

It is the recommendation of the CITI Program that guidance should be provided to indicate that institutions and organizations holding FWAs are responsible for establishing and implementing policies to insure that investigators, staff and students conducting human subjects research can demonstrate basic proficiency in the elements of protection of human subjects.

It is the recommendation of the CITI Program that guidance should be provided to indicate that institutions and organizations holding FWAs are responsible for establishing and implementing policies to insure that IRB Chairs, IRB Members and IRB professionals can demonstrate an advanced level of proficiency in the elements of human subjects protection, human subjects regulations and process.

It is the recommendation of the CITI Program that guidance should indicate that institutional officials are responsible for establishing the training and education programs, for setting the level of proficiency required to be eligible to conduct human subject research at their organization and for the evaluation of the educational programs.

It is the recommendation of the CITI Program that guidance should also indicate that institutional officials should be able to demonstrate that the training and education program they are responsible for is:

- High quality
- Comprehensive
- Inclusive
- Discipline specific
- Effectively distributed to the research community at their organization

(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?

CITI Response:

It is the recommendation of the CITI Program that OHRP should not engineer minimum educational requirements for investigators, staff and students to become eligible for the conduct of human subjects research. In our opinion, passing a standardized national exam or completing a standardized national course is not a desirable solution because such educational initiatives may actually be less rigorous than those currently used at many institutions.

It is the recommendation of the CITI Program that guidance be provided that requires institutions to provide discipline-specific, research role-appropriate training and education in the protection of human research subjects. New guidance should include statements that it is the responsibility of institutions
holding the FWAs to establish creditable training requirements for investigators, staff and students.

It is the recommendation of the CITI Program that guidance should also indicate that individuals should complete the institutionally determined, discipline- and role-appropriate training before the individual is eligible to conduct human subjects research. Many institutions require documentation of appropriate training prior to IRB review and/or approval of the research protocol or submission for HHS funding.

(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)?

CITI Response:

It is the recommendation of the CITI Program that OHRP should provide guidance directing that institutions not only offer basic training in the protection of human research subjects but also that such training should have a continuing education component.

For example, CITI Program participants can choose to design a refresher course requirement for their investigators staff and students. They can choose any recertification interval that fits their training and education goals. Table 1 shows the distribution of human subjects research recertification intervals for VA and non-VA organizations that participate in the CITI Program as of September 1, 2008.

Although recertification is voluntary, most (96%) institutions have a recertification requirement. The VA has a 1-year recertification requirement. Most Non-VA organizations that participate with the CITI Program require a Refresher Course at a 2 (53%) or 3 (35%) year interval.

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<tr>
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(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?

CITI Response:

CITI recommends that organizations retain the responsibility for preparing and maintaining written procedures for training and education requirements based on the type of research activity and roles of the research staff within the organization. No further recommendations or requirements specifying preparation and maintenance of written procedures for ensuring implementation of training and education is required through guidance or regulation.

(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?

CITI Response:

OHRP guidance should recommend training records be maintained and managed at the institutional level. This would ensure that the training programs developed are effectively used and managed according to institutional policy and the benefit of the institution’s human research protection program overseen by the Institutional Official and the Human Research Protection Administrator.

(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?

CITI Response:

CITI recommends guidance rather than regulation. If OHRP were to consider the regulatory approach for implementing training and education, it should survey current FWA organizations and determine the impact. Because there is so much variability in the types of research activity at any given organization, it would be difficult to estimate costs and man-hour costs. Guidance is preferable because the flexibility is necessary for each organization and its own infrastructure to address the training needs and oversee their implementation. Most major academic centers, for example, have one or more full-time staff members dedicated to education, training, and tracking of training information. A small hospital IRB reviewing 10 protocols a year would have a different system with likely less staff time required. The variability is great and thus makes it difficult to comment on estimated costs of the regulation in terms of infrastructure and man-hour costs.
CITI Summary:
In conclusion, CITI recommends the following:

- Guidance indicating the expectation of rigorous training and education is preferred to regulation as depicted in our responses to the questions above. Guidance is flexible and can accommodate an ever-changing research environment (i.e., genomic research, international research, technology advances).

- Training opportunities should be made available to all members of the research team in order to maximize the development of a group or team ethic.

- Training and education in the protection of human research subjects should be programmatic in scope and emphasize the tenets of the *Belmont Report*, the regulatory requirements codified in 45CFR46, its subparts and 21 CFR 50 and its subparts. Special topics may also be recommended according to the types of research being conducted at the institution.

- The specific curriculum and individual course content offerings should be organizationally driven and based on the nature of the research activity (i.e., biomedical or social behavioral) at the organization which holds the FWA, the interest of the research team and the role of individual members of the team. The educational program content should be performance-based and not engineered by OHRP.

- Continuing education is an imperative in a well-designed program. The frequency, type, and format of the continuing education requirement should be driven by the organization’s research activities, the nature of the research being conducted and the needs of the investigator.

Thank you again for this opportunity to comment. If you have questions, or require further information, please do not hesitate to contact us.

Sincerely,

Paul Braunschweiger, Ph.D.  Karen Hansen  Ernest Prentice, PhD
CITI Co-Founder  CITI Co-Founder  Chair, CITI Executive Advisory Committee

Cc: CITI Executive Advisory Committee Members: Jerry Castellano, PharmD; Kenneth Goodman, PhD; Bruce Gordon, MD; Lorna Hicks, MA; Michael Mann, PhD; Daniel Vasgird, PhD