New Guidance on Reviews By Central Institutional Review Boards (IRBs)

A new guidance has been issued by the Food and Drug Administration (FDA) that is designed to directly assist IRBs, investigators, sponsors, and others involved in multicenter clinical trials.

"The draft guidance: (1) Describes [sic] the roles of the participants in a centralized IRB review process; (2) offers guidance on how a centralized IRB review process might address local aspects of IRB review; (3) makes recommendations about documenting agreements between a central IRB and the IRBs at institutions involved in the centralized IRB review process concerning their respective responsibilities, and (4) makes recommendations concerning written procedures for implementing a centralized review process. Finally, the draft guidance discusses using a central IRB at clinical sites not already affiliated with an IRB" (70 Fed. Reg. 15635-15636 at p. 15635, Mar. 28; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a050328c.html).

Before proceeding with highlights of the new guidance, note that the recommendations in this guidance are not regulations. Thus, the guidance is not legally binding on either the FDA or the public (i.e., IRBs, etc.). Nevertheless, it can be of assistance to IRBs and others engaged in multicenter research projects.

Intent Is to Avoid Unnecessary Duplication of IRB Reviews

The FDA guidance is titled "Using a Centralized IRB Review Process in Multicenter Clinical Trials," and it is intended to be used when a single central IRB or a small number of central IRBs have the review responsibilities for a project. As is acknowledged by FDA, the review of multicenter trials can be complex and labor-intensive.

"Clinical investigations that are subject to the requirements of IND [Investigational New Drug] regulations must be reviewed and approved by an IRB in accordance with the requirements of 21 CFR part 56. The IRB requirements evolved at a time when most clinical trials were conducted at a single study site or at a small number of sites. In the intervening years, there has been substantial growth in the volume of clinical research generally, the volume of multicenter trials, and the size and the complexity of late-stage clinical trials. These changes have placed considerable burdens on IRBs and on the sponsors and clinical investigators who are seeking IRB review for multicenter trials?" (March, Section 2, "Background," on the Web at www.fda.gov/v/cder/guidance/index.htm, or contact FDA's Center for Drug Evaluation and Research at (301) 827-4573 for a copy).

Currently, it is typical in a multicenter trial for an IRB at each center to conduct a complete review of the protocol, the informed consent document and procedures, and any related study components. Such multiple reviews usually lead to unnecessary and resource-depleting duplications of effort. Hence, there has been increasing interest in ways to reduce IRB burdens and somehow centralize the IRB review process more.

FDA's guidance cites existing federal regulations that recognize the legitimacy of any centralized IRB reviews. Although we believe that there are clear advantages to situations in which an IRB is physically close to the actual research site, the FDA's guidance states that:

"Physical proximity of an IRB to a research site is not necessarily of significance, provided that the IRB

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is competent to understand the local context of the research. As stated in 21 CFR 56.107(a), this would require sensitivity to community attitudes, familiarity with the standards of professional conduct and practice where the research takes place, and knowledge about local laws and regulations applicable to the study.

A centralized IRB review process is an agreement in which multiple study sites in a multicenter trial rely, in whole or in part, on the review of an IRB other than the IRB that ordinarily would be responsible for the review of research conducted at that location (i.e., the IRB for the institution with which the site is affiliated). A site may rely entirely on the central IRB for initial and continuing review of a clinical trial, or it may rely primarily on the central IRB, but use the IRB with which it is affiliated for certain aspects of the review (e.g., review of informed consent for local concerns). A study site in a multicenter study that does not have its own IRB (e.g., a physician office site that is not affiliated with an institution which has an IRB) would rely on the central IRB that is providing IRB review for multiple sites in the study (ibid).

IRB’s Responsibilities to Local Community

Since the IRB’s connection to the community can be so important, we present here the main portion of the guidance devoted to that issue.

“The implementation of a centralized IRB review process involves addressing a number of issues related to the local community. The requirements for IRB membership in 21 CFR 56.107(a) specify that the membership of an IRB must have sufficient experience, expertise, and diversity to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. This requirement is intended to implement a recommendation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that IRB members be ‘men and women of diverse backgrounds and sufficient maturity, experience, and competence to assure that the Board will be able to discharge its responsibilities and that its determinations will be accorded respect by investigators and the community served by the institution or in which it is located.’ In addition, IRB membership must be ‘able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of [sic] professional conduct and practice’ (21 CFR 56.107(a)). Thus, IRB review, through the diversity of IRB membership, is intended to provide meaningful consideration of various local factors in assessing research activities, including the cultural backgrounds (e.g., ethnicity, educational level, religious affiliations) of the population from which research subjects will be drawn, community attitudes about the nature of the proposed research, and the capacity of the institution to conduct or support the proposed research. Inter-community differences could influence, among other things, assessments of whether mechanisms of subject selection will be equitable, whether adequate provision is made to minimize risks to vulnerable populations, and the adequacy of the informed consent process.

The preamble to the final rule indicates that where a centralized IRB review process is used (see 21 CFR 56.114), the review should consider the ethical standards of the local community. Therefore, a centralized IRB review process should include mechanisms to ensure a meaningful consideration of these relevant local factors. Possible mechanisms include:

- Provision of relevant local information to the central IRB in writing by individuals or organizations familiar with the local community, institution, and clinical research
- Participation of consultants with relevant expertise, or IRB members from the institution’s own IRB, in the deliberations of the central IRB
- Limited review of a central IRB-reviewed study by the institution’s own IRB, with that limited review focusing on issues that are of concern to the local community

Other mechanisms may also be appropriate. IRB meeting minutes or other records should document how relevant community issues were considered in the review (supra Section IV).

A Question of Liability

The new FDA guidance notes that there is an additional resource available from the Office for Human Research Protections (OHRP) on community matters of interest to IRBs. The OHRP guidance is titled “IRB Knowledge of Local Research Context” (Jul. 21, 2001) and it is available on the Web at www.hhs.gov/ohrp/humansubjects/guidance/local.htm.

Not surprisingly, the FDA recommends that any IRB, sponsor, investigator, or institution involved in any form of a centralized IRB review process should document that agreement in writing and provide all parties with copies of the written agreement. If the agreement apports IRB review responsibilities between a central IRB and a local IRB, then those respective roles should be described.

What is surprising, in our view, is the absence of any discussion of respective liabilities if anything goes wrong with a study. We have presented in the IRR many cases of serious problems with human research projects. The relevant question could be phrased, “How much risk do you wish to assume by relying on the review of an IRB not affiliated with you or your organization?”

The FDA is accepting comments about its IRB guidance until May 27th. Written comments should be sent to the Division of Dockets Management (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. E-mail comments can be sent to www.fda.gov/dockets/ecomments. For more information about the guidance, contact Ms. Nancy Stanisic of the Center for Drug Evaluation and Research at (301) 827-1660.

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How Equivalent Are Subject Protections Outside the U.S.A.?

Public comments are now being sought by the Office for Human Research Protections (OHRRP) on how to assess the adequacy of human research protections offered by institutions outside of the United States. Global clinical trials are on the increase, often involving a partnership with U.S. researchers, sponsors, institutions, and Institutional Review Boards (IRBs). The current Common Rule (or Federal Policy) on the protection of human subjects authorizes the judgment that foreign procedures are “at least equivalent” to the U.S. regulations at 45 CFR 46 (see 45 CFR 46.101(h)). The mechanism to be used is to publish such a finding of equivalent protection in the Federal Register. However, no such finding has ever been published since the policy was established in June of 1991.

Due to the increasing number of international trials that are linked to U.S. entities, there have been calls to use the authority in 45 CFR 46.101(h) by a number of parties. For example, the National Bioethics Advisory Commission made such a recommendation in April of 2001. The Inspector General of the Department of Health and Human Services (DHHS) made a similar recommendation a few months later. However, no procedural steps have ever been developed to guide how such a judgment of “equivalent protection” could be made.

Federal Agency Seeks Public’s Answers to Specific Questions

Therefore, in 2002 the director of the OHRRP formed a working group on this topic. The group produced a draft report on July 17, 2003 titled, “Report of the Equivalent Protections Working Group” (on the Web at www.hhs.gov/ohrrp/international/EPPWReport2003.pdf and a separate appendix table is at www.hhs.gov/ohrrp/international/FPGWFramework.pdf). Since then, OHRRP has been seeking input from the other agencies who have adopted the Common Rule. The OHRRP is now seeking public input on the recommendations of the group’s report. The OHRRP is not endorsing or rejecting the working group’s report but the OHRRP is interested in public comment on the following questions:

1. Is the recommended approach appropriate for implementing the authority under 45 CFR 46.101(h)?
   1.a. Is it preferable to make determinations of equivalent protections on the basis of submissions by individual institutions or on the basis of national or international procedural standards that may be relied upon by multiple institutions without repeated assessments?
   1.b. Could an alternative approach provide equal or greater effectiveness and efficiency for implementation of this authority?
   1.c. If so, what approach and why would effectiveness or efficiency be improved?
   1.d. Do the recommended criteria appropriately and adequately describe the protections provided to human subjects by the Federal Policy?
   1.e. Do the regulatory provisions the working group cited as contributing to particular protections provided by the Federal Policy relate directly to those protections? (See Table 1.)

3.b. Should other regulatory provisions be cited as relating to particular protections?

3.c. What, if any, alterations or additions to the proposed criteria would be helpful in assessing whether procedures followed in foreign countries provide protections at least equivalent to those provided by the Federal Policy?


The tables that are mentioned above refer to the core of the approach being recommended, in which columns of information (containing possibly equivalent protection data) are compared with each other to judge the equivalency of different protection approaches. The judgment on equivalency would include comparing the protections afforded by IRBs with other such reviewing bodies.

Some Protection Components May Be More Vital Than Others

The working group proposed a five-step approach to assessing the equivalency of human research protections:

(1) Articulation of the specific protections embodied in 45 CFR part 46 subpart A.
(2) Assessment of the protections provided by the institution’s procedures.
(3) Comparison of the protections provided by the institution’s procedures with those provided by 45 CFR part 46 subpart A and determination [of] whether or not the institution’s procedures provide at least equivalent protections.
(4) Approval of the relevant department or agency head for the substitution of the institutional procedures in lieu of the procedures of 45 CFR part 46 subpart A.
(5) Assurance from the institution that the substituted procedures will be followed in the conduct of human subjects research funded by HHS. The assurance will be completed and filed with OHRRP.” (ibid).

Among the many components to be contrasted between U.S. and non-U.S. procedures were seven particular protections that the working group said should be explicitly included, such as ensuring:

“adequate authority and the independence of the IRB/Research Ethics Committee... [and that the non-U.S. institution will ensure] voluntary participation after adequate disclosure of information related to the study” (ibid).

Comments on the recommendations are being accepted until May 24 and may be submitted in writing to Ms. Gail Carter, Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, The Tower Building, Rockville, Maryland 20852 at (301) 402-4521; or via fax to (301) 402-0527. Comments also may be sent electronically via e-mail to EQFRN@osophys.dhhs.gov.

For more information about this human subject protection proposal, contact OHRRP’s Glen Drew at (301) 402-4994, or send a fax to (301) 402-2071, or send an e-mail to gdrew@osophys.dhhs.gov.
Comments Sought on Record Keeping for Protection Rules

The Office for Human Research Protections (OHRP) is developing the record keeping and reporting requirements regarding applications for OHRP's "Fellowship Program." This is a new program and it is designed to:

"...provide individuals who are interested in learning about OHRP's regulatory processes and programs with an opportunity to expand their knowledge and experience regarding the complexities of the ethical and regulatory issues relating to human subject protections in biomedical and behavioral research." (70 Fed. Reg. 19962, Apr. 15; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a050415c.html).

OHRP is currently seeking approval from the Office of Management and Budget (OMB) for this information collection effort and, as is normal, the OMB is seeking public input on the paperwork requirements at the same time. Comments should be sent by May 15 to John Kraemer, OMB Desk Officer, OMB Human Resources and Housing Branch, Attention: (OMB #0990-NEW), New Executive Office Building, Room 10235, Washington, D.C. 20503.

Institutions Must Have Procedures in Place

Comments are also being sought on another aspect of human subject protection regulations that OMB is also considering for approval. This other matter is not a new information collection effort like the one noted above, however, and it is estimated that it involves more than 1.1 million hours of record keeping and reporting each year in the U.S. This estimate was based on multiplying the number of affected institutions and organizations (about 5,000) times an average of 2.5 hours of paperwork per year per institution or organization.

"The Common Rule (see 56 FR 28003) establishes Federal policy for the protection of human subjects in research that is conducted or supported by Federal departments or agencies that are signatories to the Common Rule. The 1991 Common Rule requires all institutions engaged in research which is covered by the Federal policy to establish procedures to report, disclose and maintain required information including information regarding the informed consent of research subjects and an institution's assurance of the establishment of an Institutional Review Board." (70 Fed. Reg. 19961, Apr. 15, emphasis added; at http://www.access.gpo.gov/su_docs/fedreg/a050415c.html).

The comment deadline for this separate record keeping requirement is June 15. Public comments should go to the Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Budget, Technology, and Finance, Office of Information and Resource Management, Attn: Naomi Cook (0990-0260), Room 531-H, 200 Independence Avenue, S.W., Washington, D.C. 20201.

In both instances, OMB is accepting comments on four areas for information collection efforts such as:

"(1) The necessity and utility of the proposed information collection for the proper performance of the agency's [i.e., OHRP] functions; and (2) the accuracy of the estimated burden." (ibid).

Ethics, Education Research, and Random Assignment

The Department of Education has issued a "notice of final priority" regarding its research funding that is drawing criticism, including the allegation that the priority raises serious ethical concerns. This new funding priority became effective on February 24th and it affects the federal Fiscal Year 2005 and beyond.

"We take this action to focus Federal financial assistance on expanding the number of programs and projects Department-wide that are evaluated under rigorous scientifically based research methods in accordance with the Elementary and Secondary Education Act of 1965 (ESEA), as reauthorized by the No Child Left Behind Act of 2001 (NCLB). The definition of scientifically based research in section 9201 (37) of NCLB includes other research designs in addition to the random assignment and quasi-experimental designs that are the subject of this priority. However, the Secretary considers random assignment and quasi-experimental designs to be the most rigorous methods to address the question of project effectiveness. While this action is of particular importance for programs authorized by NCLB, it is also an important tool for other programs and, for this reason, is being established for all Department programs. Establishing the priority on a Department-wide basis will permit any office to use the priority for a program for which it is appropriate." (70 Fed. Reg. 3586-3589 at p. 3586, Jan. 25; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a050125c.html).

Complaints About Research Ethics

The previous version of this proposal (see 68 Fed. Reg. 62445, Nov. 4, 2003) led about 300 parties to submit their comments. Of those 300 respondents, 186 claimed that random assignment should sometimes be ruled out because of ethical problems.

"For example, randomly assigning experimental subjects to educationally inferior treatments, or denying control groups access to important instructional opportunities, is not ethically acceptable even when the results might be enlightening. Another 13 respondents commented that the priority recognizes that there are cases in which random assignment is not ethical and, in such cases, identifies quasi-experimental designs and single-subject designs as alternatives that may be justified by the circumstances of particular interventions" (supra at p. 3588).

The department said that it agreed with both of the sets of comments and noted that the department is a signatory to the Common Rule on the protection of human subjects. Hence, all of the research projects that it funds must be reviewed by an Institutional Review Board (IRB) which ensures ethical research. Further, in situations where the pool of available human subjects is greater than the number of subjects that can be enrolled, it is ethical to offer any experimental procedures to less than the entire population of eligible subjects.

For more information about this priority, contact: Margo Anderson, Department of Education, at (202) 205-3010.
Reducing Risks for Human Subjects

The Food and Drug Administration (FDA) has issued three final guidances to help develop new or improved ways to assess and monitor the risks associated with the development of new drugs and biological products.

"As one of the five initiatives announced in November 2004 to further strengthen our drug safety program, these guidances are further evidence of FDA's commitment to transparency in risk management decisionmaking," said Dr. Steven Galson, Acting Director, Center for Drug Evaluation and Research. "Continuing to improve the way safety is assessed and monitored will lead to the earlier identification of safety problems and enable a more proactive approach to minimizing these risks," added Dr. Galson." ("FDA Issues Final Risk Minimization Guidances," Mar. 24; on the Web at www.fda.gov/bbs/topics/news/2005/NEW01169.html).

The three guidances are titled, "Premarketing Risk Assessment," "Development and Use of Risk Minimization Action Plans" (RiskMAPs), and "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment." All are available via www.fda.gov/cder/guidance/index.htm.

More Input From the Public Is Included

The guidance on Premarking Risk Assessment focuses on human research subject safety issues through the entire research period. Its key components include:

- Providing specific recommendations to industry for improving the assessment and reporting of safety during drug development trials.
- Improving the assessment of important safety issues during registration trials and to provide best practices for analyzing and reporting data that are developed as a result of a careful preapproval safety evaluation.
- Building on (but not superceding) a number of the existing FDA and ICH [International Conference on Harmonization] guidances related to preapproval safety assessments" ("FDA Issues ....", supra).

The new guidance on RiskMAPs includes a number of features, including:

"Broader input from patients, health care professionals, and the public when making recommendations about when to initiate, revise, or end risk minimization interventions" (ibid).

The third guidance on pharmacovigilance emphasizes safety concerns after a drug or biologic has been approved and is administered in treatments rather than as part of any clinical trial. That new guidance describes:

"...observational post-approval scientific and data gathering activities relating to the detection, assessment and understanding of adverse events with the goals of identifying and preventing these events to the extent possible" (ibid).

These guidances are part of FDA’s response to accusations that pharmaceutical firms and the FDA itself have ignored or even hidden negative research results and thus harmed research subjects and patients.

Researcher’s Misconduct Leads to Criminal Charges

As noted elsewhere in this HRR, we usually summarize instances of research misconduct in our “In Federal Agencies” section for the federal Office of Research Integrity (ORI). However, one recent finding of research misconduct involved behavior that was described as so “egregious” that the involved investigator has been barred for life from receiving any federal funding. He also has agreed to be permanently barred from participation in all federal health care programs, and he will pay a fine of $180,000. He will also pay $16,000 in attorney’s fees to counsel for Walter F. DeNino, a research assistant whose complaint of scientific misconduct led to the University’s investigation. Further, the researcher has agreed to submit numerous letters of retraction for many articles published in scientific journals. Finally, he has agreed to plead guilty to criminal charges for fraudulently obtaining research funds with grant applications that contained fabricated data.

The case in question involves Eric T. Poeckman, Ph.D., aged 49, a former tenured professor at the University of Vermont. The fabricated research data were included in federal grant applications and journal articles from 1992 to 2002 (see 70 Fed. Reg. 15092-15095, Mar. 24th; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a050324c.html).

Praise for University and Whistle-Blower

The potential impact that Poeckman’s falsified studies and publications may have had on recommendations of health care professionals, on other research subjects, and on patients in general is not presently known. He sought and received funding in several areas.

“Dr. Poeckman falsified and fabricated research data in grant applications and research papers related to several topics including his study of the impact of the menopause transition on women’s metabolism..., his study of the impact of aging in older men and women on a wide range of physical and metabolic measures..., and his proposal to study the impact of hormone replacement therapy... on obesity in post-menopausal women... Dr. Poeckman also presented falsified and fabricated data in grant applications and in academic papers related to his study of metabolism in Alzheimer’s patients and the effect of endurance training on metabolism” (“Press Release—Dr. Eric T. Poeckman,” ORI, Mar. 17; on the Web at http://ori.dhs.gov/misconduct/cases/press_release_poeckman.shtml).

The United States Attorney’s Office for the District of Vermont made a point of recognizing the hard work and dedication of the University’s professors and staff who led the initial investigation. ORI also said that:

“ORI and the U.S. Attorney’s Office also acknowledge the important role that individual scientists have in identifying and responding to research misconduct. ORI depends largely on the assistance of honest research scientists in the lab in discovering and reporting suspected misconduct, as occurred in this case. Without their assistance, ORI and HHS [Health and Human Services] would have great difficulty in taking appropriate actions to protect the public health” (ibid).
CASE STUDY

The consequences of a federal investigation into any research compliance violation can be severe for research institutions and individuals. Examinations of case studies of such investigations are useful continuing education tools.

* * * * * * *

Institutional Review Board (IRB) Members Must Receive Continuing Education

Case: “Single Dose Pharmacokinetic Study of Lubeluzole in Patients with Mild, Moderate, and Severe Renal Impairment” (Part 6)

Investigating Agency: Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS)

Case Concluded: December 15, 2000

As we discussed in last month’s HRR, the University in this case was ordered to immediately halt all federally-funded human research projects until many compliance problems were solved. The investigation that led to the research shutdown order was started by the federal Office for Protection from Research Risks (OPPPR) and finished by the subsequently reorganized OHRP. When informing the University of the shutdown, OPPR said that:

“By January 7, 2000, … [the University] must provide OPPR with a complete list of all the suspended protocols, including the project title, the IRB number, applicable Federal award number, and the principal investigator name. Please be aware that any such suspensions must also be reported to the funding department or agency.

Required Action 8: …[the University] must develop and forward the following corrective action plans to OPPR by January 7, 2000:

(a) A satisfactory plan to ensure IRB review of all Federal grant applications proposing human subject research prior to submission to the funding agency.
(b) A satisfactory plan to ensure that all IRB members, all IRB staff, and all research investigators are appropriately educated, on an immediate and ongoing basis, about the regulatory requirements for the protection of human subjects.
(c) A satisfactory plan to address all deficiencies and concerns described above. This plan must include (i) revised IRB policies and procedures; and (ii) revised written guidance for investigators.

Required Action 9: By January 7, 2000, … [the University] must provide OPPR … [with]:

(a) A complete list of all HHS [Health and Human Services]-supported projects that involve prisoners as subjects. Include the project title, principal investigator name, IRB project number, and applicable HHS project number.
(b) A current detailed organizational chart.
(c) The current IRB membership rosters.
(d) A copy of the IRB agenda and minutes for the IRB meetings held in November and December 1999.
(e) A list of all IRB support staff, including a description of duties and percentage of time devoted to IRB functions” (letter from Michael Carome, M.D., OPPR’s Chief of the Compliance Oversight Branch, to the University’s Vice President for Research, Dec. 17, 1999, pp. 13-14).

OPPR also informed the University that it planned to conduct an on-site evaluation of the University’s entire human research protection program (HRPP) on January 24-26, 2000 (i.e., about one month after the letter we cited above was sent to the University). During the on-site visit, OPPR planned to meet with University administrators, the IRB Chairperson, IRB members, IRB staff, several investigators who had been conducting human subjects research, and others as necessary. The OPPR also told the University that the OPPR staff would be reviewing a “large number” of IRB files. OPPR planned to conclude the two-day site visit with an hour-long meeting with the University’s Vice President for Research to discuss the OPPR’s findings.

University Hires Outside IRB to Help

A short time after receiving the OPPR’s notice of the impending site visit, the University signed a contract with an independent IRB to assist with many upcoming changes to their HRPP. On January 2, 2000, the University sent a 10-page letter to OPPR that responded to the OPPR’s “Required Actions.” The University’s Vice President for Research began the letter by stating that:

“The heart of our action plan for correcting our recognized deficiencies is the commitment of the President of …[the University] to provide all funds necessary to get and keep us in compliance and to initiate an extensive education program to provide immediate and continuing training for our staff in human subject and regulatory issues. This new education program, which will be required for all our IRB members, IRB staff, investigators and their staff, will involve OPPR and FDA [Food and Drug Administration] recognized experts in federal regulations from government, industry and other academic institutions. It will be designed to ensure that all investigators and IRB members and their staffs understand FDA and OPPR regulations on the protection of human subjects” (pp. 1-2).

One of the University’s most extensive responses dealt with initial and perpetually ongoing education on human subject protections:

“Our plan is to ensure that … [the University] provides the highest standard of safe and ethical treatment of human subjects in clinical research. To ensure that all IRB members, IRB chairpersons, IRB staff and all investigators and their staff are appropriately trained, we have designed a comprehensive program including mandatory initial training with a mandatory continuing
educational component and centralized resources. Participation in this new program will be documented through [our] Office of Continuing Education. An examination and evaluative materials will document attendance, in addition to sign-in sheets. This multiple track training program will result in:

- [University] certification to serve as part of the IRB (for IRB staff, chairpersons, and members)
- [University] certification to participate in clinical research (for investigators and staff) ( supra at p. 6, emphasis added).

The IRB training track included a new training program to be presented by external consultants. The program will be designed to include use of the OPPR Guidebook, FDA regulations, and HHS regulations. Secondly, IRB members would be required to participate in a mandatory training course in IRB standard operating procedures (or SOPs). Third, each IRB member would be required to participate in at least one IRB continuing education session annually. The session would be offered via the University’s monthly “Excellence in Research” seminars. The University’s Office of Continuing Education would offer credit for the course participation. Fourth, each IRB member would be required to register for the Web-based IRB Forum. Other resources would be publications (including copies of the monthly Human Research Report) for all of their IRB members and staff.

Researchers Want to Continue Their Projects

During this investigation an issue arose involving human safety. The Vice President for Research received a request to permit some researchers to not only continue to provide experimental cancer treatments to suffering patients but also to enroll new patients. In part, the letter stated that:

“Due to recent OPPR actions, ... [our] investigators have suspended enrollment of new subjects to all investigational studies .... Although the problems that OPPR has identified certainly need to be addressed, we are concerned that ... patients with cancer may be harmed by their lack of access to clinical trials .... We believe that the risks of permitting ... investigators to continue to treat cancer patients within the context of extramurally-reviewed clinical trials are outweighed by the potential benefits .... [Thus] we propose that:

- ... [The University] should ask OPPR permission for ... [our cancer] investigators to continue to enroll new subjects to previously activated therapeutic trials that have been reviewed by the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute or similar NIH [National Institutes of Health] regulatory bodies ....
- All patients would be managed according to the CTEP-approved protocol including CTEP-approved amendments. New patients would be consented according to the most recent ... IRB-approved informed consent form with marginal notations of any interval protocol amendments that impact upon the consent. As procedures and operations of the ... IRB are reconstituted, the protocols can be reviewed in detail, and any requisite amendments made to the informed consent forms” (Jan. 6, 2000).

The University’s Vice President forwarded a copy of this letter to OPPR, along with his own note that said that he was receiving such requests on a daily basis. OPPR’s response came the next day and it was quite clear.

“For all federally supported research projects that have been suspended by ... [the University] in accordance with the requirements of Department of Health and Human Services (HHS) regulations at 45 CFR Part 46 and OPPR’s December 17, 1999 letter to you, enrollment of new subjects must remain suspended except in extraordinary cases approved in advance by OPPR. OPPR continues to expect approval requests for such cases to be rare.” Furthermore, any research activities involving previously enrolled subjects may continue only where it is in the best interests of individual subjects. For an affected protocol, this suspension must remain in effect until the protocol has undergone appropriate initial or continuing review by one of the Institutional Review Boards (IRBs) designated under the OPPR-approved MPA” (Feb. 7, 2000, p. 1).

Research Versus Treatment

It is important to add that OPPR was not saying that the patients, in many cases, could not receive treatment. Instead, the OPPR distinguished between research and treatment to clarify when patients could continue to still receive experimental treatments.

“Neither the above suspension of Federally supported research nor HHS regulations at 45 CFR Part 46 prevent any physician from offering to any patient interventions or procedures identical to those described in a suspended research protocol, unless the interventions or the procedures involve investigational drugs, biologics or devices. However, unless OPPR has approved enrollment of the patient into the suspended research protocol, the patient should not sign a research informed consent document and may not be considered a research subject, and data may not be collected for research purposes.

Since many CTEP protocols use interventions that (i) are often limited to Food and Drug Administration-approved drugs, biologics, and/or devices, and (ii) only use monitoring procedures that are part of standard clinical practice, oncologists may certainly use such interventions and monitoring procedures to care for their patients. Again, such patients may not be considered research subjects, and data may not be collected about them for research purposes” (see supra at p. 2).

Next month in the HRR—OPPR tells the University that its responses remain unsatisfactory and they reveal significant deficiencies in its overall human subject protection system.
IN COURT

The courtroom is where serious disputes are often settled, and the field of research compliance is not an exception. Knowledge of the legal principles inherent in such cases can give compliance professionals and others a significant advantage when dealing with legal problems in research compliance.

** Privacy of Researchers Versus Public’s Right to Know Their Names **

Reference: 30 F.3d 183
Court: United States Court of Appeals, District of Columbia Circuit
Date: Decision on August 5, 1994

We routinely publish in the HRR the names of researchers found guilty of scientific misconduct. Unless there is some major lesson to be learned from the incident warranting coverage in a feature article, we publish those findings in our “In Federal Agencies” section. Findings of research misconduct usually include a falsification or fabrication of research results but they can involve plagiarism as well. Typically, the charges stem from misconduct committed in grant applications or in published study results.

We have reported a steadily rising increase in incidents of such misconduct, as can be seen in the annual reports issued by the Office of Research Integrity (ORI) within the Department of Health and Human Services (HHS). However, in addition to the actual findings of misconduct, there are even more inquiries and investigations that do not yield a finding of misconduct. A central issue for such scientific misconduct inquiries and investigations is the protection of the privacy of all the involved individuals to the extent permitted by law.

This month in the HRR we will summarize an important court case so that we may better understand just what the phrase “to the extent permitted by law” really means. As is true for a considerable amount of information maintained by the federal government, it is usually the Freedom of Information Act (the FOIA) that must be used by the public to access information about investigations of scientific misconduct, especially for investigations that do not produce a finding of misconduct. The extent to which the FOIA permits or forbids releasing individual names in misconduct investigations was tested in this month’s court case.

‘On February 7, 1990, Dr. McCutchen, a scientist, submitted a FOIA request to the HHS for ‘a list of all cases closed by the Office of Scientific Integrity [OSI, the predecessor office of ORI].’ On March 6, 1990, HHS turned over final reports for the four investigations in which OSI had found misconduct. By letter dated July 5, 1990, HHS notified Dr. McCutchen that it was withholding information on investigations in which OSI had made no finding of misconduct because disclosure of such information would constitute ‘a clearly unwarranted invasion of the subject individual or individuals [sic] personal privacy’ under the FOIA’s Exemption 6.

After exhausting his administrative remedies, Dr. McCutchen filed suit in the district court on January 23, 1991. According to his complaint, he sought to compel disclosure of ‘information listing cases closed by OSI where there was no finding of scientific misconduct.’ On March 29, 1991, HHS released to Dr. McCutcheon a list of OSI’s closed cases consisting of six columns: (1) the case number, (2) the institution involved, (3) the complainant, (4) the respondent, (5) the OSI staff member assigned to the case, and (6) the date the case was closed. Deleted from this list, however, were the names of all of the non-institutional complainants, the names of all respondents other than those who had died or been found guilty of wrongdoing, and the name of any institution whose disclosure might have enabled Dr. McCutchen to discover the identity of a respondent. In an accompanying letter, the HHS asserted that the deletions were based on the FOIA’s Exemptions 6, 7(C), and 7(D)” (30 F.3d 183 at pp. 185-186).

Plaintiff Says Federal Reports Were “Worthless”

The district court ruled that Exemption 7(C) allowed HHS to withhold the names of the whistle-blowers but not the names of the accused (respondents) as well. The court so ruled because it had decided that the public interest in scientific misconduct was so significant that the public had a right to know the names of the respondents and the details on how the federal government handled each case. It said public interest was particularly high due to concerns that OSI was doing a poor job of investigating misconduct.

The district court also stated that while the respondents might wish to remain anonymous, their privacy right was: “... not nearly so strong when one’s professional activities, rather than matters that concern personal conduct, are at issue” (supra at p. 186).

When McCutchen appealed the district court’s ruling, he stated that his FOIA request was not just for a list but for OSI’s final reports for those cases. He admitted that the written text of his request only mentioned a list but he insisted that HHS must have understood that he wanted the final reports because it had given him the full reports for the four cases where misconduct had been found.

However, the appeals court said that he had not raised such an argument in the district court so the appeals court said it would not consider that argument. McCutchen said that the final reports were worthless without individuals’ names since the public would never know if the federal investigations were adequate or not.

Next month in the HRR—career damage and stigma are sufficient reasons for withholding individual names when accusations are not proven.
IN CONGRESS

Many of the rules that affect research originate in the House and the Senate. Readers are encouraged to let bill sponsors know what they think of the legislation that we summarize in HRR. We also present selected testimony, key Congressional speeches, and hearing summaries in this section.

**Change Proposed for Regulations That Affect Institutional Review Boards (IRBs)**

As noted in this month’s “In Federal Agencies” section (see the Department of Health and Human Services), the movement is intensifying toward establishing one single centralized data bank on clinical trials. In late February, Senator Christopher Dodd (D-Connecticut) introduced the “Fair Access to Clinical Trials Act” (or FACT Act). Importantly, the FACT Act would apply to all drug and biologics trials and, for the first time, add medical device trial results to be available to the public. More importantly, in our view, the bill would apply to all clinical research regardless of the source of the research’s funding.

“Events of the past year have made it clear that such a database is needed. First, serious questions were raised about the effectiveness and safety of antidepressants when used in children and youth. It has now become clear that the existing data indicates that these drugs may very well put children at risk. However, because the data from antidepressant clinical trials was [sic] not publicly available, it took years for this risk to be realized. In the meantime, millions of children have been prescribed antidepressants by well-meaning physicians. While these drugs undoubtedly helped many of these children, they also led to greater suffering for others. Recently, it has been suggested that the risk of antidepressants might even extend beyond children.

The news is similarly disturbing for a popular class of painkillers known as Cox-2 inhibitors. These drugs, taken by millions of Americans, have been associated with an increased risk of cardiovascular adverse events, such as heart attack and stroke. It has been suggested that one of these medicines, which has since been pulled from the market, may be responsible for tens of thousands of deaths.

Unfortunately, antidepressants and Cox-2 inhibitors are just two examples of a story that has become all too common. It has been suggested that negative data might actually have been suppressed; and if this is discovered to be the case, those responsible should be dealt with harshly. However, because of what is known as ‘publication bias,’ the information available to the public and physicians can be misleading even without nefarious motives. The simple fact is that a study with a positive result is far more likely to be published, and thus publicly available, than a study with a negative result. Physicians and patients hear the good news, but rarely the bad news. In the end, the imbalance of available information hurts patients” (statement made by Dodd when he introduced the bill (S. 470) on Feb. 28, CONGRESSIONAL RECORD, p. S1797-1798).

The bill is detailed and it is 19 pages in length. Its stated purposes are:

1. to create a publicly accessible national data bank of clinical trial information comprised of a clinical trial registry and a clinical trial results database;
2. to foster transparency and accountability in health-related intervention research and development;
3. to maintain a clinical trial registry accessible to patients and health care practitioners seeking information related to ongoing clinical trials for serious or life-threatening diseases and conditions; and
4. to establish a clinical trial database of all publicly and privately funded clinical trial results regardless of outcome, that is accessible to the scientific community, health care practitioners, and members of the public” (S. 470, Section 2).

**Noncompliant Researchers Face Fines**

While the trial registry could include information about Phase I trials, such data usually would be excluded.

“(ii) The registry shall include information for all clinical trials conducted to test the safety or effectiveness (including comparative effectiveness) of any drug, biological product, or device (including those drugs, biological products, or devices approved or cleared by the Secretary [of Health and Human Services]) intended to treat serious or life-threatening diseases and conditions, except those Phase I clinical trials conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and the operating specifications of an unapproved or a not yet cleared medical device” (supra, Section 3).

Rather than creating a new clinical trials registry, the bill proposes to expand the existing registry operated by the National Library of Medicine (the NLM) and found at http://www.clinicaltrials.gov. The expanded registry would contain descriptive information, detailed human subject recruitment information, location and contact data, and related items.

In contrast, the clinical trials results database would be new but it would also be operated by the Department of Health and Human Services. The amount of information to be submitted to the results database would be substantial.

The bill would enforce the requirements to submit data to the registry and to the results database by changing IRB regulations to specify that IRBs could only approve research when researchers can prove to the IRB that preliminary information has been submitted to the registry and to the database. Once the study is completed, the results must be sent by the investigator or by the sponsor to the results database. Failure to do so would bring hefty fines.
IN FEDERAL AGENCIES

Listed below are summarized notices from major federal agencies. Included are changes in regulations, policies, and related research compliance news items.

Department of Health and Human Services. In recent months we have presented a number of trends, in both the private and public sectors, that are pointing toward the development of a public registry of all clinical trials and their eventual results. The public's reaction to revelations of hidden negative results of certain clinical trials has been strongly negative and has produced Congressional hearings and legislative proposals, among other developments.

The nationally known and respected organization known as the AAMC (for the Association of American Medical Colleges) recently announced that it supported the formation of such a registry and recommended that it be national in scope, supported by federal funds, and that there be only one such registry (versus the several partial ones that exist today).

"It is only through a comprehensive national registry system that the needs of researchers, physicians, other health professionals, and patients can be addressed reliably and consistently.

Given the present lack of consensus on the optimal structure and content of clinical trial registries, state-based initiatives to establish such registries will only create a patchwork quilt of confusion for users and result in databases of varying standards, credibility, and reliability.

The national interest in ensuring the integrity and reliability of the conduct and reporting of clinical trials demands a national solution. Consequently, federal legislation should focus on articulating the purposes of the national clinical trials registry and authorizing its creation and funding. Regulation of the registry's development should be delegated to the Secretary of the Department of Health and Human Services, with extensive discussion and input from [the] Food and Drug Administration, the National Institutes of Health, academic and other private sector experts, patients, biopharmaceutical and other relevant industries, physicians and other health professionals."

(Comments by Jordan J. Cohen, M.D., president of the AAMC, in "AAMC Supports National Registry for Clinical Trials," Apr. 7, emphasis added). For more information, contact Retha Sherrod of the AAMC at (202) 828-0975, or send e-mail to rsherrod@aamc.org.

Food and Drug Administration. The first in a series of meetings to examine drug safety and the FDA was scheduled for May 18-19 in Silver Springs, MD. The intent of the meetings is to improve the FDA's methods for monitoring the safety of marketed drugs. For more information, contact FDA's Shalini Jain at (301) 827-7001, or send e-mail to jains@cdrf.dhs.gov.

Food and Drug Administration. Comments are due by June 3rd on a new draft guidance titled, "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics." This guidance is the first in a series to provide recommendations on endpoints for clinical trials to support claims of effectiveness. Subsequent new guidelines in this series will focus on individual specific types of cancers, whereas this first one describes general regulatory principles that apply to all such studies. The notice about the guidances stated that:

"These guidances are expected to speed the development and improve the quality of protocols submitted to the agency to support anticancer effectiveness claims." (70 Fed. Reg. 17095. Apr. 4th; on the Web via http://www.access.gpo.gov/ls_doc/fedreg/a050404c.html).

The 24-page guidance explains that while traditional effectiveness endpoints have been clinical benefits such as prolongation of survival or improvement in symptoms, other endpoints (e.g., blood pressure) can indicate effectiveness too. The guidance discusses ways to establish new effectiveness endpoints without compromising the safety of any human research subjects. The guidance itself, released in April, is available via www.fda.gov/cder/guidance/index.htm.

For more information, contact Grant Williams of FDA's Center for Drug Evaluation and Research at (301) 594-5758.

Food and Drug Administration. The agency announced recently that it has referred to the Foundation for the National Institutes of Health two written requests for the conduct of pediatric studies of KEMISTRO (bactefen) and DROXIA (hydroxyurea). FDA sent these requests to conduct pediatric research to the Foundation because it believes that the drugs have not been sufficiently tested for safe and effective use with children (see 70 Fed. Reg. 15865. Mar. 29; on the Web via http://www.access.gpo.gov/ls_doc/fedreg/a050329c.html).

FDA had asked Schwarz Pharma, Inc., to conduct studies of the firm's KEMISTRO on the treatment of papillomatosis in the pediatric population. The agency also asked Bristol-Myers Squibb Company to conduct pediatric studies of its DROXIA for the treatment of sickle cell disease. However, the two firms that developed the drugs have declined to conduct the studies. They have the legal right to do so, based on the best Pharmaceuticals for Children Act (the BPCA, or Public Law 107-109).

For more information, contact: Grace Carmouze, Center for Drug Evaluation and Research (HFD-960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 at (301) 594-7337, or send e-mail to gcarmouze@cdrf.dhs.gov.

Food and Drug Administration. Effective March 24, a number of regulations have been modified regarding biological products. Many of the changes are due to the fact that:

"...regulatory responsibility, review, and continuing oversight for many biological products [have been] transferred from CBER [Center for Biologics Evaluation and Research] to CDER [Center for Drug Evaluation and Research]....This consolidation initiative was undertaken to provide greater opportunities to further develop and coordinate scientific and regulatory activities between CBER and CDER, leading to a more efficient, effective, and consistent review program for human drugs and biologics" (70 Fed. Reg. 14978: 14986 at page 14978, Mar. 24; on the Web via http://www.access.gpo.gov/ls_doc/fedreg/a050324c.html).

These changes affect 20 different parts of Title 21 of the Code of Federal Regulations. For example, included in the list of affected parts is Part 312 ("Investigational New Drug Application"), 314 ("Applications for FDA Approval to Market a New Drug"), and 822 ("Postmarket Surveillance").

For details, contact: Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), FDA, 1401 Rockville Pike, Suite 200N, Rockville, MD 20892-1446 at (301) 827-6210.

Food and Drug Administration. The agency is making available:

"...summaries of medical and pharmacological reviews of pediatric studies submitted in supplements for CARPLATIN (carboplatin), TRUSOPT (dorzolamide), PREVACID (lan索zoprazole), FERRILECT (sodium ferric gluconate), IMITREX (sumatriptan), DETROL and DETROL LA (tolterodine). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (the BPCA). For all the pediatric supplements submitted under the BPCA, the BPCA requires the FDA to make available to the public a summary of the medical and pharmacology reviews..."

In addition, the agency is also announcing the availability of summaries of pediatric medical and pharmacological reviews of pediatric studies for the following antidepressants: CELAXA (citalopram), REMERON (mirtazapine), SERZONE ( nefazodone), PAXIL (paroxetine), and ZOLFOXY (sertraline). Studies for these drugs were submitted before the BPCA was implemented. Therefore, they are not subject to its requirements. However, due to the public's interest in these pediatric studies, FDA asked
the sponsors to consent to the public disclosure of a summary of the medical and clinical pharmacology reviews for these studies. Based on sponsors’ consent, the FDA is making the summaries publicly available** (70 Fed. Reg. 15636, Mar. 28, emphasis added; on the Web via http://www.access.gpo.gov/su_docs/fe drag/a050328c.html).

The summaries are available on the Web at www.fda.gov/cder/pediatric/index.htm. For details, contact: FDA’s Grace Carmouze at (301) 594-7337, or send e-mail to carmouzeG@cder.fda.gov.

Food and Drug Administration. Effective on March 24th, Dr. Eduardo Caro Acevedo of Puerto Rico is barred for five years from providing services in any capacity to a person that has an approved or pending drug product application.

“FDA bases this order on a finding that Dr. Caro was convicted of a felony under Federal law for engaging in a conspiracy to defraud the United States and has demonstrated a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the Act [Federal Food, Drug, and Cosmetic Act] related to drug products” (70 Fed. Reg. 15106-15107 at p. 15106, Mar. 24; on the Web via http://www.access.gpo.gov/su_docs/fgredg/a050324c.html).

In addition to receiving illegal kickbacks from a medical equipment company, Caro also violated research regulations.

“In July 2002, FDA issued Dr. Caro a Notice of Disqualification to Receive Investigational New Drugs. This action was based upon repeated and deliberate submissions of false information to drug sponsors in required reports for studies of investigational new drugs that are subject to section 305 of the act. In addition, Dr. Caro repeatedly and deliberately failed to comply with the regulations governing the conduct of clinical investigators and the use of investigational new drugs in conducting two protocols sponsored by Daiichi Pharmaceutical Corp. Among other things, he submitted false information in required reports, deviated from protocols, maintained inaccurate and inadequate study records, failed to properly account for the disposition of study medications, failed to obtain adequate institutional review board approval, and failed to obtain proper consent from study subjects or their legally authorized representatives. As a result, he is no longer entitled to receive investigational new drugs ….” (supra at p. 15107, emphasis added).

For more information, contact FDA’s Elizabeth Sadove at (301) 594-2041.

Food and Drug Administration. Comments are due by May 16 on a proposed information collection.

“This notice solicits comments on the information collection requirements relating to the general licensing provisions regarding biologics license application, changes to an approved application, labeling, and revocation and suspension, and the use of Forms FDA 356h [“Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use”] and 2567 [“Transmittal of Labels and Circulars”] ….

With respect to the … collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology” (see 70 Fed. Reg. 12693-12697 at page 12693, Mar. 15, emphasis added; on the Web via http://www.access.gpo.gov/su_docs/fgredg/a050315c.html).

For more information, contact: FDA’s Jonna Lynn P. Capezzuto at (301) 827-4659.


“Since the November 2004 release of the new version, the instructions have been updated to reflect changes in policy and/or to provide better clarity. Not all updates are published in the [NIH] Guide; however, all are noted on the web site. Applicants are reminded to periodically check this web site for the latest version … Significant revisions have been made primarily in Part II, Human Subjects Research Supplement, to further address NIH implementation of OHRP [the Office for Human Research Protections] Guidance on research involving coded private information or biological specimens. Minor revisions and formatting changes have also been [sic] made in the PHS 398, Parts I and III. On Form Page 3, Research Grant Table of Contents, the ordering of items in the Human Subjects Research section of the Research Plan has been revised (“Updated Instructions to the PHS 398 [DHHS Public Health Service Grant Applications] Now Available." NIH Notice NOT-OD-05-039, Mar. 16, emphasis added; on the Web at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-039.html).

National Institutes of Health. A guidance is now available regarding the provision of certain experimental drugs to human subjects in developing countries after they have completed their research participation. Increasing concerns have been raised about the ethics of involving such persons in clinical trials and then abandoning them after the study has been completed, especially in countries where health care is scarce or unavailable.

“It is important that individuals who volunteer to participate in NIH-supported or funded HIV antiretroviral trial treatments have the option to continue to receive antiretroviral treatment following the completion of the treatment trial. For antiretroviral treatment trials conducted in developing countries, NIH expects investigators/contractors to address the provision of antiretroviral treatment to trial participants after the completion of the trial. The NIH recommends investigators or contractors work with host countries’ authorities and other stakeholders to identify available sources of antiretroviral treatment” ("Guidance for Addressing the Provision of Antiretroviral Treatment for Trial Participants Following Their Completion of NIH-Funded HIV Antiretroviral Treatment Trials in Developing Countries," NIH Notice No. NOT-OD-05-038, Mar. 16; on the Web at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-038.html). The guidance itself is on the Web at http://grants.nih.gov/grants/policy/antiretroviral/index.htm).

Office for Human Research Protections. The 2005 Award for Excellence in Human Research Protection process is underway. This program was founded by the OHRP and is administered by the Health Improvement Institute (HII). Awards will be given in three categories: best practices, innovations, and life-time achievement in matters pertaining to the protection of human research participants. For more information, contact: Jennifer Mo, HII, 5800 Madaket Road, Suite 200, Bethesda, MD 20816-3201 at (301) 320-0971, or fax to (301) 320-0978, or send e-mail to hii@hii.org, or see their Web site at www.hii.org.

Secretary’s Advisory Committee on Human Research Protections. This committee scheduled a meeting for April 18-19 in Alexandria, Virginia. The agenda included: updates from the subcommittee working on the special regulations for research with children as the subjects; a report on an examination of the basic regulations (at Subpart A) of the regulations on the protection of human research subjects; a nomination to accept the final report on the recommendations about modifying Subpart C (research with prisoners); contrasting discussions on the HRPP (or human research protection program) accreditation of researchers as presented by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and the Partnership for Human Research Protections (PHRP); the issues involved in investigator education, the protection of human research subjects; and incentives and disincentives for the monitoring and auditing of Institutional Review Boards (IRBs).

For more information, contact: Bernard Schwartz, D.V.M., Ph.D., Acting Executive Secretary, SACHRP, Department of Health and Human Services, Office of Public Health and Science, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852 at (301) 496-7005, or send a fax to (301) 402-0527, or send e-mail to sachrp@osophs.dhhs.gov.
May 4-7, 2005, in Orlando, Florida: "7th Annual NPSF Patient Safety Congress—Let’s Get On With It! Round 2." Conference will be presented by the National Patient Safety Foundation, with meetings to be held at the Marriott World Center, 8701 World Center Drive, Orlando, FL 32821 at (800) 621-0638. The topics will include: creating and sustaining patient and family advisory councils to reduce medical errors; eliminating adverse drug events; how to adapt research findings on patient safety into clinical settings; and related areas. Contact: Maureen O’Shanesy, Director of Management Services, NPSF, Suite 900, 8495 Greensboro Drive, McLean, VA 22102-5120 at (703) 506-3280, or fax to (703) 506-3266, or send e-mail to info@npsf.org.

May 6-7, 2005, in Arlington, Virginia: "2005 GRAND (Group on Research Advancement and Development) Annual Meeting." This meeting is sponsored by the Association of American Medical Colleges (AAMC) and Harvard Medical School and it will be held at the Ritz-Carlton Pentagon City, 1250 South Hayes Street, Arlington, VA 22202 at (703) 415-5000. The topics will include: frontiers in stem cell research; innovative approaches in patient-oriented research; the use of centralized Institutional Review Boards (IRBs); ensuring human research participant protections in multicenter academic clinical research; and constructing a patient medical record system to support research. For registration details, contact: Debra Holllins at (202) 828-0671, or send e-mail to dhollins@aamc.org; for logistics, contact: Rebecca Zurcher at (202) 828-0047, or send e-mail to rzurcher@aamc.org.

May 9-10, 2005, in Boston, Massachusetts: “Patient Registry Programs: Strategy, Design, Operations, and Output.” This course is offered by the Barnett International Conference Group, with meetings to be held at the Hilton Boston Logan Airport. The topics include: determining site and human subject criteria; how registry conduct must differ from phase to phase of a clinical trial; working with researchers and review boards; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 9-10, 2005, in Princeton, New Jersey: “Good Clinical Practice (GCP) for Medical Devices.” This course will be presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9305, or send an e-mail to conf@globalexec.com, or see their Web site at www.globalexec.com/irr. Topics include: how to comply with the FDA’s GCP regulations on device clinical trials; how to interact appropriately and successfully with an Institutional Review Board (IRB); how to protect human subjects in device trials; and how to comply with International Research Trial Requirements. Contact: Conference Registrar, Institute for International Research, PO Box 3685, Boston, MA 02241-3685 at (866) 647-0921, or fax to (941) 365-2507, or send e-mail to register-ppi@iirusa.com, or see their Web site at www.iirusa.com or www.pharmacotaining.org.

May 9-10, 2005, in Boston, Massachusetts: “Project Management for Clinical Trials.” Course will be presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9305, or send e-mail to conf@globalexec.com, or see their Web site at www.globalexec.com/irr. Topics include: fundamentals of the clinical trial process; the FDA and OHRP regulations on the protection of human subjects and the role of Institutional Review Boards (IRBs); recruitment and enrollment of human research subjects; adverse event reporting; and how to deal with fraud, noncompliance, and misconduct. Contact: Conference Registrar, Institute for International Research, PO Box 3685, Boston, MA 02241-3685 at (866) 647-0921, or fax to (941) 365-2507, or send e-mail to register-ppi@iirusa.com, or see their Web site at www.iirusa.com or www.pharmacotaining.org.

May 11, 2005, in Kansas City, Missouri: “FDA Drug Educational Forum.” This workshop is presented by the Food and Drug Administration (FDA) and will be held at the Kansas City Health Department Auditorium, 2400 Troost Avenue, Kansas City, MO 64108-2666 at (816) 513-4095, or send an e-mail to kcmo. The topics include: how to plan for successful and efficient product approval; numerous regulations regarding drug development and how to effectively comply with the rules; and other areas. Contact: David Arveco, FDA, 4040 N. Central Expressway, Suite 900, Dallas, TX 75204-3128 at (214) 253-4951, or send e-mail to oraswnbr@ora.fda.gov.

May 12-13, 2005, in Boston, Massachusetts: “Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMA’s.” This course is offered by the Barnett International Conference Group, with the meetings to be held at the Hilton Boston Logan Airport. The topics include: significant versus nonsignificant risks; working with Institutional Review Boards (IRBs); informed consent; and other areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 12-14, 2005, in Bloomington, Indiana: “12th Annual Workshop—Teaching Research Ethics.” Workshop presented by the Poynter Center for the Study of Ethics and American Institutions at Indiana University, and cosponsored by numerous research institutions. Meetings to be held at the Indiana Memorial Union, 900 East Seventh Street, Bloomington, IN 47405 at (812) 856-6381. Topics include how to instruct students and others on: conflicts of interest in research; rules of research with human subjects; the use of animals in research; the responsible conduct of research; how to investigate allegations of scientific misconduct; responsible data management; trainee and authorship issues; and related areas. Space is limited so early registration is encouraged. Contact: Dr. Kenneth D. Pimple, TIE Project Director, Poynter Center, Indiana University, 618 E. 3rd Street, Bloomington, IN 47405-3602 at (812) 856-4896, or fax to (812) 855-3315, or e-mail to pimple@indiana.edu, or see their Web site at http://poynter.indiana.edu.

May 16-17, 2005, in Boston, Massachusetts: “Good Clinical Practice (GCP) for Medical Devices.” This course will be presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9305, or send an e-mail to conf@globalexec.com, or see their Web site at www.globalexec.com/irr. Topics include: how to comply with the FDA’s GCP regulations on device clinical trials; how to interact appropriately and successfully with an Institutional Review Board (IRB); how to protect human subjects in device trials; and how to comply with International Research Trial Requirements. Contact: Conference Registrar, Institute for International Research, PO Box 3685, Boston, MA 02241-3685 at (866) 647-0921, or fax to (941) 365-2507, or send e-mail to register-ppi@iirusa.com, or see their Web site at www.iirusa.com.

May 16-17, 2005, in Boston, Massachusetts: “Patient Recruitment & Retention: Successful Planning and Management.” This course will be offered by the Barnett International Conference Group, with the meetings to be held at the Hyatt Harborside at Boston Logan Airport. Topics include: challenges in human subject recruitment for clinical trials; best subject recruitment practices; subject protection measures and special issues related to the participation of women and minorities as human subjects; HIPAA requirements; and other areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barrettinternational.com.

May 16-17, 2005, in Baltimore, Maryland: “Risk Management and Drug Safety.” This course is presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9305, or send an e-mail to conf@globalexec.com, or see their Web site at www.globalexec.com/irr. Topics will include: the fundamentals behind process safety, risk assessment, and risk management; how to assess risks in both pre-clinical and clinical stages; and how to comply with FDA and ICH requirements. Contact: Conference Registrar, Institute for International Research, PO Box 3685, Boston, MA 02241-3685 at (866) 647-0921, or send e-mail to register-ppi@iirusa.com, or see their Web site at www.iirusa.com.
May 16, 2005, in Washington, D.C.: “Managing Legal Risks and Avoiding Conflicts of Interest in Medical Affairs.” This conference will be presented by The American Conference Institute, with the meetings to be held at the Jurys Washington Hotel at (202) 483-6000. The topics will include: the selection and contracting of clinical investigators and investigative sites; recruitment of investigators; recruitment of human subjects; compliance guidelines for clinical trials; postmarketing and privacy issues. Contact: Conference Registrar, The American Conference Institute at (888) ACO-2490, or fax to (877) 927-1563, or see their Web site at www.americanconference.com.

May 16-19, 2005, in West Chester, Pennsylvania: “Regulatory Affairs Training Course—Part I: The IND Phase, Part II: The CTD/NDA Phase.” This course will be presented by The Drug Information Association (DIA), with meetings to be held at the Schmucker Science Center South, Room 117, West Chester University, West Chester, PA 19383 at (6100) 4346-2939. This introductory course is designed for persons with a background in preclinical research who have novice to intermediate experience in regulatory affairs. Topics include: basics of submitting applications for approval of products; the regulation of drugs and biological products; postmarketing; and related issues. Contact: Conference Registrar, Drug Information Institute, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, or fax to (215) 442-6100, or e-mail to dia@diaphome.org, or see their Web site at www.diaphome.org.

May 16, 2005, in Boston, Massachusetts: “IRB 101.” This workshop will be presented by Public Responsibility in Medicine & Research (PRIM&). The meetings will be held at the Boston Park Plaza & Towers at (617) 426-2000. The topics will include: a review of the history and development of the federal Institutional Review Board (IRB) system in the United States; the ethical principles underlying the conduct of human subjects research; and federal requirements for IRB operations. Contact: Conference Registrar, PRIM&; Suite 202, 126 Brookline Avenue, Boston, MA 02215 at (617) 423-4112, or fax to (617) 423-1185, or e-mail to info@prim.or, or see their Web site at www.primor.org.

May 17-18, 2005, in Boston, Massachusetts: “IRB Administrator 101.” This workshop will be presented by Public Responsibility in Medicine & Research (PRIM&). The meetings will be held at the Boston Park Plaza & Towers at (617) 426-2000. The topics will include: advising principal investigators, research staff, Institutional Review Board (IRB) chair and members, and institutional officials; managing protocol review; handling allegations and complaints; conducting quality improvement or assurance reviews; and developing policies and procedures. Contact: Conference Registrar, PRIM&; Suite 202, 126 Brookline Avenue, Boston, MA 02215 at (617) 423-4112, or fax to (617) 423-1185, or e-mail to info@prim.or, or see their Web site at www.primor.org.

May 18, 2005, in Boston, Massachusetts: “Patient Recruitment: Planning and Implementing a Global Campaign.” This course will be offered by the Barnett International Conference Group, with the meetings to be held at the Hyatt Regency at (617) 227-2000. The course will focus on regulatory, ethical, and practical considerations for planning and implementing a global patient recruitment plan; the best practices for global human subject recruitment; centrally managed versus locally managed clinical trials; and related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 18-19, 2005, in Philadelphia, Pennsylvania: “Comprehensive CRC Training.” This course is offered by the Barnett International Conference Group, with the meetings to be held at the Airport Marriott. The course is designed primarily for Clinical Research Coordinators (CRCs) with limited experience in managed investigations and will update their skills, and those new to the CRC role and wish to develop their skills. Topics will include: Institutional Review Board (IRB) operations and protocol review requirements; sponsor-site-IRB relationships; the informed consent process; managing and reporting adverse events; FDA audits; and other related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 18-19, 2005, in Chicago, Illinois: “Risk Management and Drug Safety.” Course is presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9305, or send e-mail to conf@globalexec.com, or see their Web site at www.globalexec.com. Topics include: fundamentals behind product safety, risk assessment, and risk management; how to assess risks, and what to do about them; and current quality systems in compliance with FDA and ICH requirements. Contact: Conference Registrar, Institute for International Research, P.O. Box 3665, Boston, MA 02241-3665 at (617) 647-0921, or fax to (941) 365-2507, or send e-mail to registrar@pti.com, or see their Web site at www.iirusa.com or www.pharma-training.org.

May 19-20, 2005, in Indianapolis, Indiana: “Fundamentals/1st Steps of Clinical Research.” This seminar is sponsored by the Association of Clinical Research Professionals (ACRP). Topics will include: ethics in clinical research; the operation of Institutional Review Boards (IRBs); adverse experience reporting; human research subject recruitment; informed consent; and related areas. Contact: Conference Registrar, ACRP, 1012 14th Street, N.W., Suite 807, Washington, D.C. 20005 at (202) 737-8100, or fax to (202) 737-8101, or send e-mail to office@acrpn.org, or see their Web site at www.acrpn.org.

May 19-20, 2005, in Indianapolis, Indiana: “Intermediate CRA Training.” This seminar is for Clinical Research Associates (CRAs) presented by the Association of Clinical Research Professionals (ACRP). Topics include: regulatory compliance; informed consent; principles of case report form development; the protocol development process; and advanced clinical monitoring. It is designed for professionals who have more than 18 months of experience. Contact: Conference Registrar, ACRP, 1012 14th Street, N.W., Suite 807, Washington, D.C. 20005 at (202) 737-8100, or fax to (202) 737-8101, or e-mail to office@acrpn.org, or Web site at www.acrpn.org.

May 19-20, 2005, in Indianapolis, Indiana: “Intermediate CRC Training.” This seminar is for Clinical Research Coordinators (CRCs) presented by the Association of Clinical Research Professionals (ACRP). Topics include: in-depth coverage of informed consent; federal regulations; appropriate advertising methods for recruiting human research subjects; how to implement the results of FDA audit findings; and related areas. It is designed for professionals who have more than 18 months of experience. Contact: Conference Registrar, ACRP, 1012 14th Street, N.W., Suite 807, Washington, D.C. 20005 at (202) 737-8100, or fax to (202) 737-8101, or e-mail to office@acrpn.org, or Web site at www.acrpn.org.

May 19-20, 2005, in Detroit, Michigan: “11th Annual Convention of The National Association of IRB Managers, Inc.” Convention is presented by The National Association of IRB Managers, Inc. (NAIM), with meetings to be held at Detroit’s Airport Crown Plaza Hotel, 800 Merriman Road, Romulus, MI 48174 at (734) 729-2600. Topics include: overview of federal regulations for new IRB Chairs and IRB Coordinators; a mock meeting of an IRB: the IRB’s role in pediatric research; reports and documents required of IRBs; the involvement of non-English speaking research subjects; how to deal with noncompliant researchers; HIPAA updates; the differences between IRB certification exams held by NAIM and by PRIM&; scientific misconduct and conflicts of interest; protecting vulnerable research subjects; and related areas. Contact: Thomas Ball, M.D., CIP, Program Director, NAIM, P.O. Box 668906, Atlanta, GA 30364-0806, at (404) 766-9890, or fax to (404) 768-0140, or send e-mail to ballthomas@aol.com, or see their Web site at www.naim.org.

May 19-20, 2005, in Chicago, Illinois: “Clinical Research Monitoring Course for Site Coordinators, Monitors, and Auditors.” Course will be presented by the Society of Clinical Research Associates (SoCRA), with the meetings to be held at the Radisson Hotel and Suites Chicago, 160 East Huron Street, Chicago, IL 60611 at (312) 787-2900. Topics to be covered include: the major obligations of sponsors and monitors as required by the Food and Drug Administration (FDA); the International Conference on Harmonization (ICH) guidelines on many aspects of clinical research; site visits and how to meet with investigators; evaluation of research data for compliance and accuracy; prospective study management; new ways to improve efficiency and organize the research monitoring process; and related areas. Contact: Conference Registrar, SoCRA, P.O. Box 101, Furlong, PA 18925 at (800) 762-7292, or fax to (215) 345-7369, or e-mail to SCRORMAIL@aol.com, or Web site at www.SoCRA.org.

May 19-20, 2005, in Research Triangle Park, North Carolina: “Project Management for Clinical Trials.” This course will be presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9305, or send e-mail to conf@globalexec.com, or see their Web site at www.globalexec.com. Topics include: fundamentals of the clinical trial process; FDA and OHP regulations on the protection of human research subjects and the role of Institutional Review Boards (IRBs); the recruitment and enrolling of human research subjects; adverse event reporting; and how to deal with fraud, noncompliance, and research misconduct. Contact: Conference Registrar, Institute for International Research, P.O. Box 3665, Boston, MA 02241-3665 at (617) 647-0921, or fax to (941) 365-2507, or send an e-mail to registrar@pti.com, or see their Web site at www.iirusa.com or www.pharma-training.org.
May 20, 2005, in Indianapolis, Indiana: “Successful Strategies for Medical Device Trials.” This seminar is presented by the Association of Clinical Research Professionals (ACRP). Topics to include: the various steps in the Investigational Device Exemption (IDE) process; the differences between drug and device trial management; and how to manage and monitor IDE research projects; and related areas. Contact: Conference Registrar, ACRP, 500 Montgomery Street, Suite 800, Alexandria, VA 22314 at (703) 254-8100, or fax to (703) 254-8101, or send e-mail to office@acrpnet.org, or see their Web site at www.acrpnet.org.

May 23-24, 2005, in Boston, Massachusetts: “Pediatric Clinical Research: GCPs for Pediatric Multi-Center Clinical Trials.” This course is offered by the Barnett International Conference Group, with the meetings to be held at the Hilton Boston Logan Airport. Topics will include: ICH guidelines; how to develop INDs; ethics in pediatric clinical research; the impact of the Children's Health Act of 2000 on clinical trials; and HIPAA; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 23-25, 2005, in Boston, Massachusetts: “Clinical Research Coordinator (CRC): Intermediate.” This course will be offered by the Barnett International Conference Group, with meetings to be held at the Hilton Boston Logan Airport. Topics to include: an overview of the drug development process; in-depth human subject recruitment and retention strategies; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 23-25, 2005, in Philadelphia, Pennsylvania: “CRA & CRC: Beginner Program.” This course is offered by the Barnett International Conference Group for aspiring Clinical Research Coordinators (CRCs) and Clinical Research Associates (CRAs), with the meetings to be held at the Airport Marriott. The topics include: the FDA regulations and guidelines for Good Clinical Practice (GCP); the role, composition, and operations of Institutional Review Boards (IRBs); the informed consent process, the basic elements of consent, and additional elements of consent which may be required; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 23-25, 2005, in Philadelphia, Pennsylvania: “15th International Contracting & Negotiating Clinical Trials.” This conference is sponsored by the Strategic Research Institute and the Model Agreement Group Initiative, with the meetings to be held at The Crowsne Plaza Hotel, 1800 Market Street, Philadelphia, PA 19103 at (215) 561-7580. The topics will include: managing risk and human subject injuries; confidentiality and data use; ethics in research; regulatory and legal issues; and more related areas. Contact: Strategic Research Institute, 333 Seventh Avenue, Ninth Floor, New York, NY 10001-5004 at (800) 559-4950, or see their Web site at www.srir institute.com.

May 24-25, 2005, in Philadelphia, Pennsylvania: “Global GCP Monitoring: Domestic and International Compliance.” This course will be offered by the Barnett International Conference Group, with meetings to be held at the Hilton Garden Inn. Topics include: ethics in clinical research; Good Clinical Practices (GCPs) offered by the FDA and the ICH (International Conference on Harmonization); cultural impacts on GCP; operations of specific regulatory bodies of various countries; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 25-26, 2005, in San Francisco, California: “International Drug Approval Regulatory Procedures.” This course is offered by the Barnett International Conference Group, with the meetings to be held at the San Francisco Marriott Fisherman’s Wharf. Topics include: the European regulatory structure in health care; marketing authorization in Europe; the International Conference on Harmonization (ICH); requirements for clinical studies; international cooperation; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

May 25-27, 2005, in Boston, Massachusetts: “Comprehensive Monitoring for Medical Devices.” This course is offered by the Barnett International Conference Group, with meetings to be held at the Hilton Boston Logan Airport. The course is designed for Clinical Research Associates (CRAs) with about 1-2 years of experience, engineers, and other device professionals. Topics include: an overview of the FDA’s regulations on medical devices; the device development and approval process; the roles and responsibilities of the research team; composition and function of Institutional Review Boards (IRBs); the informed consent process; detecting fraud; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence their Web site at www.barnettinternational.com.

May 26-27, 2005, in Boston, Massachusetts: “Planning, Conducting, and Managing Studies Outside of the U.S.” This seminar will be presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9901, or send e-mail to conf@globalexec.com. The topics will include: how to comply with ICH guidelines and country-specific requirements; how to avoid fraud and misconduct in global trials; and how to recruit and retain human research subjects. Contact: Conference Registrar, Institute for International Research, P.O. Box 3065, Boston, MA 02241-3065 at (866) 647-0921, or fax to (941) 365-2507, or send e-mail to register-pts@iirusa.com.

June 2, 2005, in Milwaukee, Wisconsin: “Human Research Protection: Striving for Excellence.” This Research Community Forum is sponsored by the federal Office for Human Research Protections (OHRP) and the Medical College of Wisconsin, with the meetings to be held at the college. The topics include: changes in the regulations on the protection of human subjects; the ethical basis of clinical research; OHRP updates; new initiatives on how to protect subjects; presentation of an informed consent Web site; community-based research with vulnerable populations; and the VA and its own research compliance. Contact: Cheri Runge at (414) 277-5176, or send e-mail to cirunge@mcw.edu.

June 2-3, 2005, in Raleigh, North Carolina: “Conducting Clinical Trials Under ICH GCP.” This course is offered by the Barnett International Conference Group, with meetings to be held at the Sheraton Capital Center. This course is designed primarily for the clinical, regulatory, and quality control personnel who require an understanding of the Good Clinical Practice (GCP) regulations. Topics to include: an introduction to the International Conference on Harmonization (ICH) and the FDA GCPs; USA GCPs covering sponsor, investigator, and Institutional Review Board (IRB) responsibilities; international GCPs covering similar issues; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556, or fax to (610) 565-4584, or see their Web site at www.barnettinternational.com.

June 3-4, 2005, in Houston, Texas: “The 29th Annual Health Law Teachers Conference.” Conference is presented by The American Society of Law, Medicine & Ethics (ASLME) and the University of Houston Law Center. The meetings will be held at the Texas Medical Center, with lodging available at The Warwick Hotel, 5750 Main Street, Houston, TX 77005 at (713) 526-1991. Topics include: bioethics; current issues in medical research; the ethical and legal issues of genetic research; liability issues; drug regulation; patient safety; the sale and trade of human organs and tissues; and other medico-legal areas. Contact: Conference Director, ASLME, 765 Commonwealth Avenue, Suite 1634, Boston, MA 02215 at (617) 262-9900, ext. 18, or e-mail to conferences@aslme.org.

June 5-8, 2005, in Princeton, New Jersey: “2005 Pharma, Biotech and Device Colloquium.” This colloquium is offered by the Health Care Compliance Association (HCCA), with the meetings to be held on the campus of Princeton University in Princeton, NJ 08544 at (609) 258-3000. Topics will include: FDA focus on risk-based compliance; how to build a culture of ethics; clinical trial disclosures; risk management; regulators’ perspectives on future risk areas; and more related areas. Contact: Conference Coordinator, HCCA, 5780 Lincoln Drive, Suite 120, Minneapolis, MN 55436 at (888) 580-8373, or fax to (952) 988-0146, or send e-mail to info@hcca-info.org, or see their Web site at www.hcca-info.org.

June 6-7, 2005, in Philadelphia, Pennsylvania: “Early Stage Risk Management: Optimizing Premarking Risk Assessment Practices.” This conference is presented by The Pharmaceutical Education Associates, with the meetings to be held at The Sheraton University City Hotel, 3549 Chestnut Street, Philadelphia, PA 19104 at (215) 387-8000. The topics will include: the role of biomarkers and genomics in risk management; pharmacovigilance planning; management of safety information in clinical trials; and human risk assessment based on nonclinical data. Contact: Conference Registrar, Pharmaceutical Education Associates, 18705 N.E. Cedar Drive, Battle Ground, WA 98620 at (800) 686-2276, or see their Web site at www.pharmaceudassociates.com.

June 6-7, 2005, in Morristown, New Jersey: “Project Management for Clinical Trials.” This course will be presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8950, or fax to (203) 431-9901, or send e-mail to conf@global
exec.com, or see their Web site at www.globalexec.com). Topics include: fundamentals of the clinical trial process; FDA and OHRP regulations on protecting human research subjects and the role of Institutional Review Boards (IRBs); recruitment and enrolling of human research subjects; adverse event reporting; and how to deal with fraud, noncompliance, and misconduct. Contact: Conference Registrar, Institute for International Research, P.O. Box 3685, Boston, MA 02241-3685 at (866) 647-0921, or fax to (941) 365-2507, or send e-mail to register-pi@iriusa.com, or see their Web site at www.iriusa.com or www.pharmaining.org.

June 6-7, 2005, in Philadelphia, Pennsylvania: “Risk Management and Drug Safety.” This course is presented by PTI International. Hotel accommodations are available from Global Executive, 90 Grove Street, Suite 01, Ridgefield, CT 06877 at (203) 431-8590, or fax to (203) 431-9305, or send e-mail to conf@globalexec.com, or see their Web site at www.globalexec.com. Topics to include: the fundamentals behind product safety, risk assessment, and risk management; how to assess risks in both pre-clinical and clinical stages; and how to comply with FDA and ICH requirements. Contact: Conference Registrar, Institute for International Research, P.O. Box 3685, Boston, MA 02241-3685 at (866) 647-0921, or send e-mail to register-pi@iriusa.com.

June 6-7, 2005, in Philadelphia, Pennsylvania: “Clinical Project Management: Intermediate.” This course is offered by the Barnett International Conference Group, with meetings to be held at the Hilton Garden Inn. Topics to include: problems, quality issues, and accreditation programs for Institutional Review Boards (IRBs); human subject enrollment and retention; risk management in clinical trials; and more related areas. Contact: Conference Registrar, Barnett International Conference Group, Rose Tree Corporate Center, 1400 North Providence Road, Suite 2000, Media, PA 19063-2043 at (800) 856-2556.

June 13-14, 2005, in Sacramento, California: “Promoting a Productive and Responsible Research Environment.” This conference is sponsored by the federal Office of Research Integrity and the Office of Research at the University of California at Davis. The meetings will be held at the Sheraton Grand Sacramento Hotel, 1230 J Street, Sacramento, CA 95814 at (916) 447-1700, or fax to (916) 447-1701. The topics will include the various responsibilities of the Research Integrity Officer (RIO): such as: preventing research misconduct; fostering a responsible conduct of research (RCR) culture; handling allegations of research misconduct; promoting best practices; monitoring conflicts of interest; assisting investigational committees; monitoring the impact of RCR on human subject recruitment; protecting students from potential faculty conflicts of interest; and developing appropriately ethical university-industry relations. Contact: Ms. Debbie Glad, Research Integrity and Compliance Officer, Office of Research, 402 Mrak Hall, University of California, One Shields Avenue, Davis, CA 95616 at (530) 754-6473, or fax to (530) 754-7391, or send email to dglad@ucdavis.edu.

June 13-17, 2005, in Boston, Massachusetts: “Sixth Annual Ethics Issues in International Health Workshop.” This workshop is sponsored by Harvard’s Department of Population and International Health, and the Center for Continuation Professional Education. The topics will include: ethical guidelines for research involving human subjects; proposed changes to institutional guidelines: individual and group rights; Institutional Review Boards (IRBs); conflict of interest and scientific misconduct; responsibility of researchers to the community; research in refugee populations; and key issues in genetic research. Contact: Suzanne Welty, Program Manager, Program on Ethical Issues in International Health Research, Harvard School of Public Health, 665 Huntington Avenue, Building 1-1106, Boston, MA 02115 at (617) 432-3998, or fax to (617) 566-0565, or send e-mail to swelty@hsph.harvard.edu.

June 16-17, 2005, in Bryn Mawr, Pennsylvania (Philadelphia area): “The Research Coordinator: Strategies for Promoting Integrity in Clinical Research.” This conference is sponsored by the federal Office of Research Integrity (ORI) and hosted by the Drexel University College of Medicine, the University of Pennsylvania, and Thomas Jefferson University. The meetings will be held at the Gregg Conference Center in Bryn Mawr; this conference addresses four areas: protect patient rights; protect protocol; operational management; and data integrity and data management. For example, the human subject protections area includes: privacy issues; subject recruitment; retention; and follow-up; conflict of interest; and therapeutic misconception. Contact to be announced at www.med.upenn.edu/oricnft.

June 23-25, 2005, in San Francisco, California: “3rd Annual Meeting of the International Society for Stem Cell Research (ISSCR).” This conference will be held at the ISSCR, with the meetings to be held at the San Francisco Marriott, 55 Fourth Street, San Francisco, CA 94103 at (800) 266-9432. The topics will include: clinical trials on tissue, stem cells, and new therapies; funding, regulation, and global trends in stem cell research; and ethical and legal issues in stem cell research. Contact: Administrative Director, ISSCR, Suite 500, 60 Revere Drive, Northbrook, IL 60062 at (847) 509-1944, or fax to (847) 490-9283, or e-mail to isscr@isscr.org.

July 22-23, 2005, in Seattle, Washington: “1st Annual Conference on Pediatric Bioethics: Current Controversies in Pediatric Research Ethics.” This course will be offered by the Center for Pediatric Ethics at the Children’s Hospital and Regional Medical Center. The meetings will be held at the Red Lion Hotel on Fifth Avenue, 1415 Fifth Avenue, Seattle, WA 98101 at (800) 504-3009. The topics will include: regulations on research with children; issues related to consent and assent; ethical conduct; defining minimal risk; changing views of justice in research with children; how failure to conduct research can be unethical; genetic issues in pediatric research; and academic and industry relations and conflicts of interest. Contact: Tracy at Convention Services Northwest at (202) 292-9198, ext. 12, or see the Web site at www.seattlechildrens.org/bioethics, or contact Ms. Sharon Burden, Children’s Center for Pediatric Bioethics, 1100 Olive Way, Suite 500, Seattle, WA 98101 at (206) 987-7585.

Special Note: The following series of the annual PRIM&R ARENA workshops and conferences are still the premier educational offerings in the nation on human subjects protections. There’s a reason why these conferences are still around after more than 20 years. If you can attend only one conference per year, then this is the series to attend. If you can attend more than one, then this series is still the one to attend.

December 3, 2005, in Boston, Massachusetts: “IRB 101 Biomedical.” This one-day course is presented by Public Responsibility in Medicine and Research (PRIM&R) with the meetings to be held at the Sheraton Boston Hotel, Prudential Center, 39 Dalton Street, Boston, MA at (617) 236-2000, or fax to (617) 236-1702. This course will include topics such as: the history of the development of the federally mandated IRB system in the U.S. and its basic underlying principles; an overview of federal regulations on the protection of human subjects; case studies involving biomedical research; and related topics. On the same day, the following course will also be offered: “IRB 101 Social Science/Behavioral.” This course includes topics such as: the history of the federal IRB system; an overview of federal regulations on the protection of human subjects; and case studies involving social science and behavioral research. Contact: Conference Registrar, PRIM&R, Suite 202, 126 Brookline Avenue, Boston, MA 02215 at (617) 423-4112, or fax to (617) 423-1185, or e-mail to info@primr.org, or see their Web site at www.primr.org.

December 4-6, 2005, in Boston, Massachusetts: “2005 Annual Human Research Protection Program (HRPP) Conference.” This conference (formerly known as the Annual IRB Conference) will be presented by Public Responsibility in Medicine and Research (PRIM&R) and it includes the 20th Annual Meeting of the Applied Research Ethics National Association (ARENA). Topics to be announced in late July. Contact: Conference Registrar, PRIM&R, Suite 202, 126 Brookline Avenue, Boston, MA 02215 at (617) 423-4112, or e-mail to info@primr.org, or see their Web site at www.primr.org.

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As the founding editor and publisher of the HUMAN RESEARCH REPORT, Dr. Maloney monitors various professional disciplines to keep readers up-to-date on human experimentation topics and events. As the author, coauthor, and editor of more than 200 publications, he has written extensively for professional audiences and for the public. His acclaimed book on human research participants, Protection of Human Research Subjects: A Practical Guide to Federal Laws and Regulations, is available from Plenum Press in New York.

His Ph.D. in Experimental Psychology was granted (with honors) in 1973 by the University of Kansas. He then conducted research and related projects during; two years at the Western Carolina Center in Morgantown, NC; nine years at Boys Town in Nebraska; two years at the Emergency Medical Services Council in Omaha, NE; six years at Creighton University; and three years at the University of Nebraska-Lincoln. He is president of The Deem Corporation (a research consulting firm he founded in 1984) and he directs the SolveAnnoy® service for solving research compliance and many other types of problems (e.g., see http://www.ResearchCompliance.com). Experiences in supervising basic and applied research studies, he has faced the difficulties of constructing complete yet understandable informed consent documents and research protocols for approval by Institutional Review Boards (IRBs). He has developed a wide range of successful grant proposals (over $20,000,000 in awards) for funding from local, state, and federal government agencies, corporations, private and corporate foundations, and individual philanthropists.

As the founding member of an IRB, and later as its chairman, Dr. Maloney is familiar with the responsibilities and challenges undertaken by IRBs that strive to protect human research subjects while still encouraging important research. He has assisted in drafting human service legislation and has analyzed lawsuits in a series of workshops lectures. A member of many professional organizations, he has also served as chairman of a national committee on legal issues and human services. The Deem Corporation is a registered member of the Better Business Bureau, the BBB Honor Roll, and the Internet-based BBB OnLine Reliability Program. Contents of this newsletter are by Dr. Maloney unless indicated otherwise.

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