

Human Research Report

PROTECTING RESEARCHERS AND RESEARCH SUBJECTS

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New Federal Guidance on Registering Institutional Review Boards (IRBs)

The Food and Drug Administration (FDA) has issued a new guidance titled, "Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions -- IRB Registration." As we have described previously, the final requirements issued both by the FDA and the Office for Human Research Protections (OHRP) became effective on July 14. The FDA's guidance:

"... is intended to assist IRBs in complying with the new requirement for IRB registration. This new rule requires each IRB in the United States that reviews FDA-regulated research to register using an Internet-based registration system that is maintained by the Department of Health and Human Services (HHS). This registration system is a modification of the one currently used by the Office for Human Research Protections (OHRP) for registration of IRBs that are designated by institutions under Federalwide Assurances (FWAs). OHRP has issued a similar rule requiring IRBs designated by institutions under FWAs to register or update their registration information using this modified system" (74 Fed. Reg. 34025, July 14; see http://www.access.gpo.gov/su_docs/fedreg/a090714c.html).

Registration is NOT Accreditation

The Frequently Asked Questions (FAQs) document addresses a number of aspects of the new IRB registration requirements. The first issue is why the FDA is now requiring all IRBs that review FDA-regulated products to register.

"Because our information at the present time is derived from research and marketing applications, FDA (we) cannot be certain that we have current information about IRBs that review FDA-regulated studies. For example, some drug and device studies are exempt from the Investigational New Drug (IND, 21 CFR Part 312) and Investigational Device Exemptions (IDE, 21 CFR 812) submission requirements and are conducted without FDA involvement. In addition, many device studies (e.g., non-significant [sic] risk and many in vitro diagnostic (IVD) studies) are conducted with only IRB approval. We, therefore, do not have real-time information about these studies or the IRBs that review them.

In addition, several reports from the HHS Office of Inspector General (OIG) regarding our oversight of the conduct of clinical studies recommended IRB registration, stressing the importance of a comprehensive listing of all IRBs that review FDA-regulated research.

The 2001 OIG report also expressed concern about our ability to assure an equivalent level of human subject protection in clinical studies of FDA-regulated products conducted outside of the U.S. as compared to those conducted in the U.S. While registration of non-U.S. IRBs (often referred to as Independent or Research Ethics Committees -- IECs/RECs) is voluntary, information we receive from them will be helpful in addressing this concern" ("Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions -- IRB Registration," July, pp. 2-3; on the Web at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM171256.p>).

FDA also believes the new registration requirement will make it easier to monitor IRBs.

"The new rule will provide FDA, as well as other interested parties (e.g., the IRB community, sponsors,

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and clinical investigators), with a comprehensive listing of all U.S. IRBs that review FDA-regulated research. It will also provide information about non-U.S. IRBs/IECs/RECs that review FDA-regulated research and choose to voluntarily register. This more complete knowledge of IRBs that actively review FDA-regulated studies will:

- Facilitate our sharing of educational and other information with IRBs. We believe that the lack of an accurate, complete, and regularly updated listing of IRBs involved with the review of FDA-regulated studies limits our outreach and educational efforts;

- Assist us in scheduling and conducting IRB inspections under our bioresearch monitoring (BIMO) inspection program, by assuring up-to-date contact information; and

- Help us to prioritize IRB inspections” (supra at p. 3, emphases added).

The FAQ guidance makes it clear that simply registering an IRB has nothing to do with accreditation or is proof that an IRB is in compliance with 21 CFR Part 56.

One Combined Internet-Based System

The section of the IRB registration guidance on applicability is quite brief.

“4. Who must register?”

Each IRB in the U.S. that either:

- a. reviews clinical investigations regulated by FDA under sections 505(i) (21 U.S.C. 355(i)) or 520(g) (21 U.S.C. 360j(g)) of the Federal Food, Drug, and Cosmetic Act (the Act); or

- b. reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products. (See 21 CFR 56.106(a))” (supra at pp. 3-4).

Importantly, as the next FAQ shows, both OHRP and FDA are using the same Internet-based system -- not two different systems.

“6. How does an IRB submit an initial registration?”

IRBs that are not already registered must submit an initial registration. IRBs can submit this registration electronically through <http://ohrp.cit.nih.gov/efile>. If your IRB lacks the ability to register electronically, it must send its registration information, in writing, to the Good Clinical Practice Program (HF-34), Office of Science and Health Coordination, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

As noted above, we are utilizing a modified version of the Internet-based system OHRP has employed for registration of IRBs designated under FWAs. Both OHRP and FDA will be using this same modified system.

The electronic registration system provides instructions to assist you in providing the appropriate information, depending on whether your IRB is subject to regulation by only OHRP, only FDA, or both OHRP and FDA.

7. What if my IRB is already registered in the OHRP system?

If your IRB is already registered in the OHRP system, the registration information must be updated to include all the information required by FDA For IRBs that are currently reviewing FDA-regulated research, the additional information must be added to the database by September 14, 2009. For IRBs that are not currently reviewing FDA-regulated research, after the compliance date of September 14, 2009, they must update their registration information before they review any research involving FDA-regulated products.

8. What is the effective date of the final rule and, by what date, [sic] must IRBs complete an initial registration or submit additional information as required by the FDA rule?

This rule is effective July 14, 2009, but in order to allow IRBs adequate time, IRBs must submit initial registration or make required revisions to their registrations by September 14, 2009” (supra at page 4, underline emphasis added).

Detailed IRB Information Is Required

The following list should prove helpful in preparing for the FDA registration process. The final rule requires:

“(1) The name, mailing address, and street address (if different from the mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mailing address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;

(2) The IRB’s name, mailing address, street address (if different from mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson’s name, phone number, and electronic mail address; and the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information;

(3) the approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an ‘active protocol’ is any protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and

(4) A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews” (supra at p. 5).

For details, contact: FDA’s Jean Toth-Allen, Ph.D., at 301-827-1585, or e-mail to jean.toth-allen@fda.hhs.gov. (See elsewhere in this HRR for a related OHRP notice.) ©

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Privacy Rule Causes Problems For IRBs and Researchers

In previous HRR articles we have discussed the impact of the HIPAA Privacy Rule on Institutional Review Boards (IRBs), researchers, and others (e.g., Privacy Boards; see the federal document at <http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp> for details and advice). More recently, we have presented key portions of the Institute of Medicine's (IOM's) report titled, "Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research" (<http://books.nap.edu/catalog/12458.html>). For example, we presented the first IOM recommendation in the April HRR regarding Congressional action to address the problems created by the Privacy Rule. We continue here with the IOM's argument on needed Congressional action.

"The committee's first and foremost recommendation (Recommendation I) is that Congress should authorize HHS [the Department of Health and Human Services] and other relevant federal agencies to develop a new approach to protecting privacy in health research that would apply uniformly to all health research. When this new approach is implemented, HHS should exempt health research from the HIPAA Privacy Rule. The new approach should enhance privacy protections through improved data security, increased transparency of activities and policies, and greater accountability, while also allowing important health research to be undertaken with appropriate oversight" (Summary, February, p. 3 of 13; on the Web at http://www.nap.edu/catalog.php?record_id=12458).

New Privacy Regulations Recommended

According to the IOM, the new approach being recommended by the IOM committee should:

- "Apply to any person, institution, or organization conducting health research in the United States, regardless of the source of data or funding;
 - Entail clear, goal-oriented, rather than prescriptive, regulations.
 - Require researchers, institutions, and organizations that store health data to establish strong data security safeguards.
 - Make a clear distinction between privacy considerations that apply to interventional research and research that is exclusively information based.
 - Facilitate greater use of data with direct identifiers removed in health research, and implement legal sanctions to prohibit unauthorized reidentification of information that has had direct identifiers removed.
 - Require ethical oversight of research when personally identifiable health information is used without informed consent. HHS should develop best practices for oversight that should consider:
 - Measures taken to protect the privacy, security, and confidentiality of the data;
 - Potential harms that could result from disclosure of the data; and
 - Potential public benefits of the research.

- Certify institutions that have policies and practices in place to protect data privacy and security in order to facilitate important large-scale information-based research for clearly defined and approved purposes, without individual consent.

- Include federal oversight and enforcement to ensure regulatory compliance" (ibid, emphasis added). The IOM report cites other countries' legislation as possible models for new legislation in the United States.

"Informative examples for such an approach include Ontario's Personal Health Information Protection Act (PHIPA) and a similar model recently proposed in the United Kingdom. Ontario's PHIPA shares a number of similarities with the HIPAA Privacy Rule. In general, both rules require the holder of personally identifiable health data to get informed consent (referred to as authorization in the Privacy Rule) before using those data for a purpose other than providing services directly related to the health care of the patient. If a researcher wishes to use personally identifiable health data without getting informed consent, both rules require the researcher to obtain a waiver of informed consent approved by an independent ethics board [e.g., an IRB or Privacy Board] before the study begins" (p. 6).

HIPAA Privacy Rule Not Uniformly Applied

The IOM report points out, however, that there are some key differences between the existing U.S. HIPAA Privacy Rule and Ontario's PHIPA.

"One major difference is that unlike the HIPAA Privacy Rule, which applies privacy obligations unevenly across the health care sector, PHIPA applies to health information custodians (HICs; e.g., providers, hospitals, and pharmacies) that collect, use, and disclose personally identifiable health information from an HIC. Thus, the privacy protections follow the data.

Another important difference is that PHIPA permits HICs to disclose personally identifiable health information without consent to 'prescribed persons or entities' that have in place privacy practices, policies, and procedures approved by Ontario's Information and Privacy Commissioner. The prescribed persons or entities may then disclose information to researchers either in deidentified form, or in identifiable form with approval of a Research Ethics Board (Canadian equivalent of an Institutional Review Board (IRB) or Privacy Board). Consistent with the principle of transparency, a prescribed entity must also make public a description of its functions and a summary of its practices, policies, and procedures. A similar approach was recommended in a report commissioned by the United Kingdom's Prime Minister on secondary uses of personal information. This report suggested the creation of 'safe harbors,' which have three defining characteristics: (1) they provide a secure environment for processing personally identifiable health data, (2) they are restricted to 'approved researchers' who meet relevant criteria, and (3) they implement penalties and allow for criminal sanctions against researchers who abuse their access to personally identifiable data" (ibid). ©

Requirements Go Beyond Usual IRB Requirements

The National Institutes of Health (NIH) has issued its final version of the document titled, "National Institutes of Health Guidelines for Human Stem Cell Research." NIH received about 49,000 comments on its previous draft of the Guidelines that were issued in the FEDERAL REGISTER on April 23. The Guidelines were issued pursuant to President Obama's Executive Order 13505 titled, "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells."

"The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.

These Guidelines implement Executive Order 13505, as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH policies and procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH stem cell research" (74 Fed. Reg. 32170-32175 at p. 32170, July 7, emphasis added; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090707c.html).

What Research Is Covered By Guidelines?

Before we address the Institutional Review Board (IRB) aspect of these Guidelines, we summarize the basic applicability of the Guidelines.

"Respondents [i.e., commenters] felt the title of the NIH draft guidelines was misleading, in that it is entitled 'National Institutes of Health Guidelines for Human Stem Cell Research,' yet addresses only one type of human stem cell. The NIH notes that although the Guidelines pertain primarily to the donation of embryos for the derivation of hESCs, one Section also applies to certain uses of both hESCs and human induced pluripotent stem cells. Also, the Guidelines discuss applicable regulatory standards when research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research. Therefore, the title of the Guidelines was not changed.

Respondents also disagreed with the definition of human embryonic stem cells in the draft Guidelines, and asked that the NIH define them as originating from the inner cell mass of the blastocyst. The NIH modified the definition to say that human embryonic stem cells 'are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers'" (pp. 32170-32171).

The IRB component to these Guidelines is addressed in a portion of the FEDERAL REGISTER announcement that is titled "IRB Review Under the Common Rule."

"Respondents suggested that the current regulatory structure of IRB review under the Common Rule (45 CFR Part 46, Subpart A) addresses the core ethical principles needed for appropriate oversight of hESC derivation. They noted that IRB review includes a full review of the informed consent process, as well as a determination of whether individuals were coerced to participate in the research and whether any undue inducements were offered to secure their participation. These respondents urged the NIH to replace the specific standards [in the Guidelines] to assure voluntary and informed consent in the draft Guidelines with a requirement that hESC research [simply] be reviewed and approved by an IRB, in conformance with 45 CFR Part 46, Subpart A, as a prerequisite to NIH funding. Respondents also requested that the NIH create a registry of eligible hESC lines to avoid burdensome and repetitive assurances from multiple funding applicants" (supra at p. 32171).

IRB Review Is Not Enough

It can be seen in the following NIH response that IRB review is not enough for research with hESCs.

"The NIH agrees that the IRB system of review under the Common Rule provides a comprehensive framework for the review of the donation of identifiable human biological materials for research. However, in the last several years, guidelines on hESC research have been issued by a number of different organizations and governments, and different practices have arisen around the country and worldwide, resulting in a patchwork of standards. The NIH concluded that employing the IRB review system for the donation of embryos would not ameliorate stated concerns about variations in standards for hESC research and would preclude the establishment of an NIH Registry of hESCs eligible for NIH funding, because there would be no NIH approval of particular hESCs. To this end and in response to comments, these Guidelines articulate policies and procedures that will allow the NIH to create a Registry. These Guidelines also provide scientists who apply for NIH funding with a specific set of standards reflecting currently recognized ethical principles and practices specific to embryo donation that took place on or after the issuance of the Guidelines, while also establishing procedures for the review of donations that took place before the effective date [July 7] of the Guidelines" (ibid). The Guidelines do say, however, that IRB review may be necessary.

"When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 CFR part 46, subpart A. Applicants should consult [the OHRP guidance at] <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>" (supra at p. 32174). ©

More Aspects of Direct Accountability for IRBs

With this article we continue our coverage of the Advanced Notice of Proposed Rulemaking (ANPRM) that was issued by the Office for Human Research Protections (OHRP) on holding Institutional Review Boards (IRBs) directly accountable for noncompliance. This is in contrast to the current situation whereby OHRP holds accountable the institution with the Federalwide Assurance (FWA) that actually conducts human subjects research. It is worth examining the issues we have not yet presented during the current period when OHRP is reviewing the public comments it received to the ANPRM because we fully expect the ANPRM to be followed by a another public proposal prior to actual regulations.

In its ANPRM, OHRP listed seven areas of issues for which it requested public input. We pick up where we left off in previous articles with the sixth category addressing the differing areas of accountability for IRBs/IORGs (institutions or organizations operating an IRB) and the institutions holding an FWA which may or may not be operating any IRB(s).

“6b. Is there a fourth category of responsibilities [versus the three we presented in the June HRR] that are inherently shared by both the IRB/IORG and the FWA-holding institution? If so, please provide examples of such shared responsibilities” (74 Fed. Reg. 9578-9583 at page 9582, March 5; available on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090609c.html).

Who Is Responsible for What?

As noted previously, OHRP has proposed a categorization of responsibilities according to those unique to IRBs or IORGs, those unique to FWA-holding institutions, and those that may fulfilled by any of the entities. Hence, another OHRP question is:

“6c. Are the regulatory provisions identified under each of the categories appropriate? If not, which regulatory provisions should be re-categorized [sic], removed, or added?

7. With regard to the responsibilities that may be fulfilled by either IRBs or institutions, the IRB Authorization Agreement between an external IRB and an FWA-holding institution is often used to clarify which entity will be responsible for carrying out these regulatory agreements.

7a. If a regulatory change to 45 CFR part 46 is pursued, should OHRP use the IRB Authorization Agreement or other forms of agreement, if they exist (e.g., contract or memorandum of understanding) to inform its compliance oversight evaluations about which entity should be held responsible for fulfilling regulatory requirements that could be met by either an external IRB or the FWA-holding institution?” (ibid).

More information is available from Julie Kaneshiro of OHRP at 240-453-6900 or send an e-mail to julie.kaneshiro@hhs.gov. ©

Special Research Review Requirements

Comments will continue to be accepted by the Food and Drug Administration (FDA) until September 1 on a new draft guidance titled, “The Radioactive Drug Research Committee [RDRC]: Human Research Without an Investigational New Drug [IND] Application.” We recall that all research reviewed by an RDRC also must be reviewed by an Institutional Review Board (IRB). As we noted in last month’s HRR, the new guidance for RDRCs has a specific section on human subjects research. We continue here with the portion that addresses the number of subjects to be enrolled in studies -- a relevant topic for IRBs as well.

“(2) **Number of subjects:** The number of research subjects enrolled in a protocol under an RDRC can vary. Of primary importance is that research with the radioactive drug is conducted for the purpose of advancing scientific knowledge and not for immediate therapeutic, diagnostic, or similar purposes in humans or to determine the safety and effectiveness of the drug in humans. FDA recommends that an RDRC protocol be approved for a *finite number* of subjects sufficient to gain basic information. In FDA’s experience, many studies under an RDRC start with 30 subjects or fewer. Recent RDRC studies have averaged 10 subjects annually per study” (guidance, June, pp. 5-6 of 36; on the Web at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM163892.pdf>).

More Human Subjects Must Be Justified

If an RDRC approves a protocol that plans an exposure of more than 30 subjects to the radioactive material, then the RDRC must submit to FDA a special information summary within 7 calendar days.

“The special summary should include a justification for continued subject enrollment to ensure that research is considered basic science and not moving towards immediate therapeutic or diagnostic purposes, or determining the safety and effectiveness of a drug in humans (i.e., carrying out a clinical trial for safety and efficacy). Reasons for increasing subject enrollment might include the study of the radioactive drug in different subpopulations related to age, sex, or disease types, such as subjects with impaired renal function or diabetes. Reasons such as statistical powering for non-basic [sic] research endpoints, grant requirements, or making decisions about patient treatment are not valid justifications for continued subject enrollment in RDRC studies. Contents of these special summary reports are available for public disclosure, unless confidentiality is requested by the investigator and it is adequately shown by the investigator that the report constitutes a trade secret or confidential commercial information” (supra at p. 6).

IRBs must conduct a continuing review of research approved by an RDRC not less than once a year. For details, contact FDA’s Orhan Suleiman at 301-796-1471. ©

New IRB Registration Rules In Effect for HHS and FDA

On July 14, new regulations on the registration of Institutional Review Boards (IRBs) were scheduled to go into effect. These regulations include the regulations of the Department of Health and Human Services (HHS) at 45 CFR 46, of the Food and Drug Administration (FDA) at 21 CFR 56.

“The HHS IRB registration requirements were added as a new subpart E to the HHS protection of human subjects regulations Subpart E requires all IRBs that review human subjects research conducted or supported by HHS and that are designated under an assurance of compliance approved for federalwide use (i.e., a Federalwide Assurance (FWA)) by OHRP [Office for Human Research Protections] to register with HHS. Required IRB registration information includes: contact information for the person providing the registration information; approximate numbers of all active protocols and active protocols involving research conducted or supported by HHS; and, [sic] approximate number of full-time equivalent positions devoted to the IRBs [sic] administrative activities” (OHRP e-mail, July 8).

IRB Information Must Be Submitted Electronically

The type of information that any particular IRB has to submit to OHRP will vary from IRB to IRB, depending on the studies that they review.

“For any IRB currently registered with OHRP, the institution or organization operating the IRB must submit all information required under HHS regulations at subpart E of 45 CFR part 46 by the current expiration date previously assigned by OHRP or within 90 days of any changes regarding the contact person who provided the IRB registration information or the IRB chairperson, whichever comes first. Institutions or organizations operating IRBs currently registered with OHRP that review FDA-regulated research will need to update registration information to include FDA-specific information once the registration rule is effective

Note that beginning on July 14, 2009, institutions and organizations needing to register a new IRB, or update or renew an existing IRB registration, must do so electronically via the OHRP website at <http://ohrp.cit.nih.gov/efile/> unless the institution or organization lacks the ability to register its IRBs electronically. The updated registration system will go live on July 14, 2009. In addition, the Office of Management and Budget (OMB) recently approved the information collection requirements in both rules. Thus, beginning on July 14, 2009, IRB registration information for both rules will be collected on the OMB-approved modified IRB registration form (OMB No. 0990-0279), which will be posted on the OHRP website” (ibid).

Details are available from OHRP’s Irene Stith-Coleman, Ph.D., at 240-44543-6900, or send e-mail to Irene.Stith-Coleman@hhs.gov. (See elsewhere in this HRR for a related FDA notice regarding the registration of IRBs). ©

New Elements in Accreditation Standards for Human Subjects

As we described in last month’s HRR, the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) is in the process of making major modifications to the existing accreditation standards for human research protection programs (HRPPs). These modifications will affect Institutional Review Boards (IRBs) of course, but researchers and administrators as well. If the proposed time line is maintained, AAHRPP plans to post the new final standards on their web site (<http://www.aahrpp.org>) sometime in October.

In addition to the new accreditation elements we described last month, we present here the rest of the new elements. We recall that the standards are composed of three “Domains” (I = Organization; II = IRB or Ethics Committee (EC); and III = Researchers and Research Staff). In turn, each Domain consists of several “Standards,” and Standards contain a number of “Elements.” Domain I contains a new Element I.8.C. as follows:

“The Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for periodically or urgently sending data and safety monitoring reports to the Organization” (“Proposed Revised Accreditation Standards,” comparison between existing and proposed standards, May 28, p. 5; on the Web at <http://www.aahrpp.org/Documents/D000214.PDF>).

IRBs Cannot Protect Human Subjects Alone

A new Element in Domain III emphasizes the responsibilities of researchers and research staff.

“Element III.2.B. Researchers and Research Staff follow the requirements of the research plan or protocol, adhere to the Organization’s policies and procedures, and the determinations of the IRB or EC” (p. 10).

Finally, regarding Elements in the revised standards, we note that one Element has been completely eliminated from the existing requirements. The deleted Element is Element II.8.A., as follows:

“The Research Review Unit has and follows policies and procedures for communication among IRBs, when appropriate, for research conducted at multiple sites (e.g., multi-site [sic] clinical trials, epidemiology studies, or educational surveys)” (supra at p. 11).

While much of the focus of HRPPs is on IRBs, it has become clear that IRBs alone cannot possibly protect human subjects without support from their organization and researchers. Hence, the revised standards describe the importance of Domain III responsibilities accordingly:

“Fundamentally, these responsibilities stem from the fact that an individual conducting research enters into arrangements that may intentionally expose human participants to some degree of risk -- whether physical, psychological, economic, legal[,] or social -- for scientific purposes” (“Proposed Revised Accreditation Standards,” June 1, p. 2; on the Web at <http://www.aahrpp.org/Documents/D000213.PDF>). ©

FDA Warning Letter

Researcher Fails to Follow Instructions of Institutional Review Board (IRB)

The Food and Drug Administration (FDA) sent a Warning Letter to a Nevada plastic surgeon due to his noncompliance with regulations on the protection of human subjects.

“This Warning Letter is to inform you of objectionable conditions observed during ... the FDA inspection conducted at your clinical site from January 22 through February 12, 2008, by an investigator from the FDA San Francisco District Office This inspection was also conducted in order to verify adequate implementation of the corrective actions you promised following violations observed during your last FDA inspection in 2003, and which were cited in a letter sent to you by FDA on June 18, 2003

Our review of the inspection report prepared by the district office revealed several serious violations of Title 21, CODE OF FEDERAL REGULATIONS (21 CFR) Part 812 -- Investigational Device Exemptions and Part 50 -- Protection of Human Subjects” (April 21, 2008, page 1 of 5).

The Warning Letter cited three areas of noncompliance. The first involved informed consent, as follows:

“1. Failure to ensure that informed consent was obtained in accordance with 21 CFR Part 50 (21 CFR 812.100)

You failed to adhere to the above-stated regulations. Examples of this failure include, but are not limited to, the following:

a.) One of the subjects enrolled in the study signed the consent form for the incorrect study. Specifically, Subject ... [redacted] signed the 1/19/01 version of the consent form on 8/12/03, which was dated as approved by the IRB on 3/20/01, for the original clinical study. Enrollment for the original study was completed in February[,] 2002, and additional subjects should have been enrolled into the ... [redacted] with a new informed consent form dated 3/10/03. The old consent form contained the incorrect address for the IRB, and differed in study purpose, the sponsor name, and patient confidentiality information.

b.) Subject ... [redacted] had the ... [redacted] on 7/11/03, but the consent was not signed until 7/21/03. A handwritten note on the consent form states, ‘I was informed about the study and the risk -- did not sign consent on 6-26-03,’ but the note is not signed or dated by the study subject. In addition, there was nothing in the subject’s clinic record to confirm that she was verbally consented prior to the ... [redacted]. Where consent is obtained orally, it must be documented on an IRB-approved short form consent document in accordance with 21 CFR 50.27(b)(2).

2. Failure to ensure an investigation is conducted in accordance with the signed agreement with the

sponsor, the investigational plan, applicable FDA regulations, and any conditions of approval imposed by FDA or the IRB (21 CFR 812.100 and 21 CFR 812.110(b)).

You failed to adhere to the above-stated regulations. Examples of this failure include, but are not limited to, the following:

a.) The IRB notified you on 3/11/03 of their new address and contact information, and required that you provide copies of an informed consent attachment to all previously enrolled study subjects. There was no documentation in your study files to indicate that previously enrolled subjects received this information. During the FDA inspection, you told the FDA investigator that the ... letter probably had not been distributed.

During your last inspection in 2003, FDA observed a similar failure to adhere to IRB instructions for providing a consent form addendum to study subjects for a different clinical study ...” (supra at p. 2).

Misuse of Confidential Patient Information

The second noncompliance area involved the confidentiality of private subject information.

“c.) The study protocol requires that study subjects complete a confidential Quality of Life questionnaire (CFR [Case Report Form] 3) ... [redacted] and at the ... [redacted] and ... [redacted] year follow-up visits. The protocol specifically states, ‘The patient should place the confidential questionnaire in the postage paid envelope provided and give the envelope to the study coordinator to be mailed directly to Since this questionnaire is confidential, a copy of the completed Quality of Life form should not be kept in the study/patient files.’ The study Start-up/Inservice Sheets and the Form 3 cover sheet repeat these instructions. Despite these instructions, a Quality of Life form for subject completed on 1/28/08, was found in the study files. Your clinic visit summaries for subject [sic] ... [redacted] also indicate that you have reviewed and used the information on that subject’s Quality of Life forms for your follow-up visit evaluation, even though the protocol requires that they be kept confidential from the investigator.

A similar failure to adhere to protocol requirements for confidentiality of Quality of Life questionnaires in another clinical study involving the same sponsor was observed during your last inspection in 2003, and cited in FDA’s letter of June 18, 2003. At that time, you stated that you and your study coordinator ‘understand that the Quality of Life Assessment is confidential and should not be kept in the study/patient’s files.’ However, during this most recent investigation, you told the FDA investigator that you were not aware that the Quality of Life form was to be confidential” (supra at p. 3).

The third noncompliance area involved a finding of inconsistent and/or inaccurate data in almost every subject’s file. The physician was given the usual 15 days to fix the problems or face sanctions, including potential permanent disqualification from conducting studies. ©

OHRP Investigation

Case: “Human Research Subject Protection Under the Multiple Project Assurance ... [for] Melanoma Tumor Vaccine” (Part 20)

Investigating Agency: Launched by the Office for Protection from Research Risks (OPRR) and concluded by the Office for Human Research Protections (OHRP)

Case Concluded: October 19, 2000

Restrictions Remain on Human Research

As we noted last month, the investigated university received partial good news when OHRP reinstated their Multiple Project Assurance (MPA) following numerous improvements to the university’s human subjects protection program (HRPP). However, OHRP placed a number of restrictions on that MPA, as follows:

“(a) All Federally supported research projects at ... [the one campus that was investigated] involving human subjects are to remain suspended in accordance with OHRP’s letter of June 29, 2000, until one of the IRBs designated under the revised MPA reviews and approves the research. Certification of such IRB approval must be submitted in writing to the appropriate official(s) at the supporting Federal department or agency prior to resumption of the research.

(b) In its June 29, 2000[,] letter, OHRP expressed concern that some research involving human subjects at the ... [university] was inappropriately designated as being exempt from the requirements of HHS regulations at 45 CFR Part 46. The ... [university] must inventory all active exempt human subject research being conducted at the ... [university] and ensure that such research satisfies the criteria for exemption under HHS regulations at 45 CFR 46.101(b).

(c) OHRP hereby removes from coverage under the MPA any Federally supported research conducted by Dr. ... [the Principal Investigator (PI)]. For any HHS-supported award to ... [the university] involving human subjects research for which Dr. ... is a principal investigator or coinvestigator, the ... [university] must submit to OHRP a Single Project Assurance for review and approval prior to the initiation of any research activities [sic] involving human subjects supported by the award.

For any human subjects research being conducted by Dr. ... and supported by another Federal Department or Agency, the ... [university] should consult with appropriate officials at that Department or Agency regarding implementation of an appropriate Assurance mechanism.

(d) By August 31, 2000, the ... [university] must submit to OHRP a follow-up report regarding its investigation into the serious noncompliance with HHS regulations for the protection of human subjects involving (i) the melanoma vaccine research conducted by Dr.

...; (ii) the actions of the now disbanded ... [university] IRB (in particular the Chair, Dr. ...); and (iii) the actions of other senior officials at the ... [university] following the delivery of the March 16, 2000[,] audit report from ... [an outside firm] to officials at the ... [university]. Your report should describe any additional actions taken by the institution in response to the identified noncompliance.

(e) By October 15, 2000, the ... [university] must submit to OHRP a progress report regarding implementation of its corrective action plans. This progress report should include the following:

(i) A summary of the progress made in implementing the planned educational programs for all IRB members, all IRB staff, and all research investigators about the ethical principles and regulatory requirements for the protection of human subjects.

(ii) A summary of the IRBs['] progress in reviewing all research at the ... [university] involving human subjects

(iv) Any revised written IRB policies and procedures” (letter to university’s Senior Vice President and Provost from OHRP’s Michael A. Carome, M.D., Chief, Compliance Oversight Branch, July 13, 2000, pp. 2-3 of 3).

Task Force Recommends Many Changes

About a week later, the university’s new Compliance Task Force submitted a report to the president of the university that contained a number of major new changes.

“At your request, the Compliance Task Force has reviewed the ... [university’s] compliance programs for research, health care, and other similarly regulated activities. Our goal was to identify systemic changes necessary to ensure the absolute highest levels of compliance and position the University as a leader in this area. While we did review the melanoma study ..., neither that study nor any of the other hundreds of research studies on the three ... [university] campuses is singled out in this report. An in-depth examination of individual programs is beyond the scope of our review; instead, we are proposing, as an initial step, a broad system-wide approach that could be applied to each area of compliance (be it traditional grant work, contract work, research involving human subjects, animal research, the provision of health care, etc.).

The last five years at the ... [university] have seen tremendous growth in research and health care, and the ... [university] has achieved national stature. With this growth, the University is stretching the capabilities of its compliance assurance systems. To continue to meet the demands of an organization with such a diverse research community, large health care practice, as well as new federal requirements, we are unanimously recommending the adoption of six key principles to provide a compliance roadmap for the University” (July 20, 2000, p. 1 of 2).

We will present those six key compliance principles in next month’s HRR. ©

In Court

Case: Abdulaziz v. City of Philadelphia (Philadelphia), University of Pennsylvania (Penn), Johnson and Johnson (Johnson), Dow Chemical Company (Dow), Albert Kligman, M.D. (Kligman), and Ivy Research Labs (Ivy), (Part 5)

Reference: 2001 WL 818476, No. CIV. A. 00-5672

Court: United States District Court, E.D., Pennsylvania

Date: First Decision on June 26, 2001; Second Decision on Oct.18, 2001 (2001 WL 1257441)

Court Starts Examining Whether Statute of Limitations Barred Research Subjects' Lawsuit

The second court decision in this case revolved around the defendants' motions for a "summary judgment."

"Summary judgment is appropriate 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law' The party moving for summary judgment has the initial burden of showing the basis for its motion Ultimately, the moving party bears the burden of showing that there is an absence of evidence to support the nonmoving [i.e., the former research subjects who were prisoners as the time of the medical experiments] party's case.... Once the movant adequately supports its motion ..., the burden shifts to the nonmoving party to go beyond the mere pleadings and present evidence through affidavits, depositions, or admissions on file to show that there is a genuine issue for trial A genuine issue is one in which the evidence is such that a reasonable jury could return a verdict for the nonmoving party A fact is 'material' only if it might affect the outcome of the suit under the applicable rule of law When deciding a motion for summary judgment, a court must draw all reasonable inferences in the light most favorable to the nonmovant [the former prisoners] Moreover, a court may not consider the credibility of the evidence in deciding a motion for summary judgment, even if the quantity of the moving party's evidence far outweighs that of its opponent.... Nonetheless, the party opposing summary judgment must do more than just rest upon mere allegations, general denials, or vague statements...." (2001 WL 1257441, October 18, 2001, p. 2 of 7).

After laying the foundation for a decision on summary judgment motions, the court then proceeded with its discussion of this particular case. We present here the court's view that the former prisoners did not help their case.

"In the instant case, Plaintiffs have failed to respond to Defendants' motions. (FN 2. Pursuant to Rule 7.1(c) of the Local Rules of Civil Procedure of the United States District Court for the Eastern District of Pennsylvania, 'any party opposing the motion shall serve a

brief in opposition, together with such answer or other response which may be appropriate, within fourteen (14) days after service of the motion and supporting brief' Not only did the Plaintiffs in the instant case fail to respond within the required fourteen days, they neglected to respond entirely.) In the interest of justice, the Court will examine the Plaintiffs' complaint and the Defendants' objections to it on the merits in order to determine if summary judgment is appropriate Because of Plaintiffs['] failure to respond to any of the Defendants['] motions, the Court is limited to a consideration of the pleadings filed by the parties and the exhibits filed by the Defendants" (supra at pp. 2-3).

"Unjust Enrichment" Claim Years Too Late

The court then considered an issue that would prove the key to this case; namely, the statute of limitations.

"The Defendants argue that they are entitled to summary judgment because Plaintiffs' claims of negligence, fraud, and unjust enrichment are barred by the statute of limitations In addition, Defendant City of Philadelphia contends that the appropriate statutes of limitations also prohibit Plaintiffs' section 1983 claim, as well as Plaintiffs' request for an action for an accounting The Court will review the statute of limitations as it pertains to each individual cause of action.

1. Unjust Enrichment

Plaintiffs contend that Defendants were unjustly enriched as a result of fees earned from Plaintiffs' participation in the medical testing at Holmesburg [Prison] Defendants contend that this claim is barred by the applicable statute of limitations The statute of limitations for a quantum meruit [i.e., 'as much as he has deserved'] action under Pennsylvania law is four years A 'quasi-contract/unjust enrichment action is likewise subject to a four-year limitations period, as it constitutes a contract implied in law' While an action based on contract accrues at the time of breach ... quantum meruit actions accrue as of the date on which the parties terminate their relationship

Here, a four-year statute of limitations applies to Plaintiffs' claims of unjust enrichment against Defendants. Viewing the evidence in the light most favorable to the Plaintiffs, the parties terminated their relationship no later than December 1974 after the medical testing had ceased (FN 3. With respect to Defendant City of Philadelphia, the relevant date to determine when the parties terminated their relationship for the purposes of this action is the date when the medical testing ceased, as opposed to the date of the individual Plaintiff's release from prison, because the conditions complained of here relate only to the medical testing, and not to the conditions of confinement generally.) Therefore, the four-year statute of limitations barred Plaintiffs' unjust enrichment claims as of December 1978. The time alleged in Plaintiffs' complaint shows that the cause of action has not been brought within the statute of limitations Therefore, the Court grants Defendants['] summary judgment as to Plaintiffs' claims for unjust enrichment" (supra at p. 3). ©

In Congress

Formal Recognition By Government For National Human Subjects Protection Accreditation Body

We continue this month with our coverage of the "Protection for Participants in Research Act of 2009" (H.R. 1715) that was introduced on March 25 by Representative Diana DeGette (D-Colorado). While she has introduced a version of this bill for several years, we note that this time the Democrats control both the House and the Senate.

One section of the bill addresses a topic we have covered many times in the HRR; namely, the accreditation of human subject protection programs (HRPPs).

"(5) Voluntary Accreditation. -- The Secretary may in accordance with this paragraph facilitate the accreditation of institutions and Institutional Review Boards [IRBs] by recognizing a private accrediting entity or entities. For purposes of the preceding sentence:

(A) The Secretary may recognize an accrediting entity if --

(i) such entity submits to the Secretary the standards and procedures that the entity requires institutions and Institutional Review Boards to meet in order to be accredited by the entity;

(ii) the Secretary determines that such standards and procedures include standards and procedures ensuring that the policies and procedures of institutions and Institutional Review Boards accredited by the entity are in compliance with Federal regulations governing human subjects research; and

(iii) the entity annually submits to the Secretary a report describing any changes in the standards and procedures described in clause (ii).

(B) The Secretary may not require that any institution, Institutional Review Board, or program for the protection of human subjects in research, or any component thereof, be accredited.

(C) Nothing in this section may be construed as authorizing the Secretary --

(i) to establish or approve accreditation standards or procedures for institutions, Institutional Review Boards, or programs for the protection of human subjects in research, or any component thereof; or

(ii) to recognize any standards or procedures for institutions or Institutional Review Boards other than the standards and procedures described in subparagraph (A)(ii)" (H.R. 1715, pp. 21-23 of 37; on the Web at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1715ih.txt.pdf).

There is an extremely important section in the bill, in our opinion, that is quite brief, as follows:

"(6) Cost Recovery. -- Institutions may recover costs

associated with compliance for human subject protections under this part from government sponsors of research as direct costs" (supra at p. 23).

The bill also would require the formation of Data Safety and Monitoring plans.

"(f) Data Safety and Monitoring Plans. --

(1) In General. -- If a human subject research project meets the criteria developed under paragraph (2), such project shall be conducted in accordance with a data safety and monitoring plan.

(2) Criteria. -- The Secretary shall develop criteria for determining whether a human subject research project must be conducted in accordance with a data safety and monitoring plan" (ibid).

No Federal Funds For Certain Classified Research

The bill also specifies what the contents of such a data safety and monitoring plan must include, as follows:

"(A) A requirement that the sponsor of the human subject research project use a data safety and monitoring committee in affiliation with the project.

(B) Minimum requirements for the reporting by the principal investigator of information on such data safety and monitoring plan to the Institutional Review Board for the project and to the institution served by the Board.

(C) A requirement that the data safety and monitoring committee described in subparagraph (A) provide reports on the findings of the committee regarding the project to such investigator, Board, and institution.

(D) (i) A requirement that the principal investigator report to the Institutional Review Board for the project and the sponsor of the project --

(I) in the case of any unanticipated problem in the project involving risks to human subjects or other individuals, immediately; and

(II) in the case of any adverse event in the project, in a timely manner appropriate to the severity of the event and whether the event is unexpected.

(ii) An unanticipated problem or adverse event referred to in subclause (I) or (II) of clause (i), respectively, shall be reported by the principal investigator, in addition to the reports required by clause (i), as directed by the Secretary by regulation. Such regulations shall ensure comprehensive and coordinated reporting to all relevant parties" (supra at pp. 23-25).

There is a special section that specifies that, regardless of any other law, no federal funds may be spent on any classified human subjects research if the following conditions are met:

"(1) the Institutional Review Board reviewing the proposal for the research pursuant to this section has under the Common Rule [for the protection of human research subjects] waived the requirement to obtain the informed consent of the human subjects in the research; or

(2) the research is exempt from the requirement under the Common Rule that the proposal for the research be reviewed by such a Board" (supra at pages 25-26).

©

In Agencies & Organizations

- **Food and Drug Administration.** Comments will be accepted until September 8 on the FDA's current record-keeping and reporting requirements related to a Public Health Service (PHS) guideline titled, "PHS Guideline on Infectious Disease Issues in Xenotransplantation."

"The PHS guideline recommends procedures to diminish the risk of transmission of infectious agents to the xenotransplantation product recipient and to the general public The collection of information described in this guideline is intended to provide to sponsors general guidance on the following topics: (1) The development of xenotransplantation clinical trials; (2) the preparation of submissions to FDA; and (3) *the conduct of xenotransplantation clinical trials*" (74 Fed. Reg. 33260-33264 at p. 33260, July 10, emphasis added; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090710c.html).

For more information, contact: Jonna Capezzuto of the FDA at 301-796-3794.

- **National Institutes of Health.** A notice has been issued regarding the new NIH Guidelines for Human Stem Cell Research. Of particular importance was one section regarding Institutional Review Board (IRB) review of this type of research.

"According to OHRP guidance (<http://www.hhs.gov/ohrp/humansubjects/guidance/stemcell.pdf>), HHS-supported research that involves neither interactions nor interventions with living individuals or obtaining identifiable private information is not considered human subjects research according to regulations at 45 CFR 46. Therefore, in vitro research or research in animals using previously derived and established human cell lines, from which the identity of the donor cannot be readily ascertained by the investigator, is not considered human subjects research and *does not require IRB review and approval*. If the identity of the donor is known to the investigators, such research is generally considered to involve human subjects and to *require IRB review and approval*" ("Human Subjects Research Considerations," in "Status of Applications and Awards Under the New NIH Guidelines for Human Stem Cell Research," NIH Notice Number NOT-OD-09-123, July 15, emphases added; on the Web at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-123.html>).

See elsewhere in this HRR for more information about IRBs and human stem cell research. For more information, contact: Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, 6705 Rockledge Drive, Suite 350, Bethesda, MD 20892, or send e-mail to GrantsPolicy@od.nih.gov.

- **National Institutes of Health.** Comments are due by August 10 on the reporting and recordkeeping requirements used by the National Cancer Institute (NCI) titled, "Investigator Registration and Financial Disclosure for Investiga-

tional Trials in Cancer Treatment."

"In order to fulfill these requirements, a standard Statement of Investigator (FDA Form 1572 modified), Supplemental Investigator Data Form, Financial Disclosure Form[,] and Curriculum Vitae (CV) are required. The data obtained from these forms allows the NCI to evaluate the qualifications of the investigator, identify appropriate personnel to receive shipment of investigational agent, ensure supplies are not diverted for inappropriate protocol or patient use[,] and *identify financial conflicts of interest*" (74 Fed. Reg. 27552-27553 at p. 27552, June 10, emphasis added; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090610c.html).

For more information, contact: Charles L. Hall, Jr., of the NCI at 301-496-5725, or send an e-mail to Hallch@mail.nih.gov.

- **Office of Research Integrity.** A finding of research misconduct has been made in the case of Jennifer Wanchick, a former Research Assistant in the MetroHealth System (an affiliated hospital of Case Western Reserve University). The misconduct occurred in research supported by the National Institutes of Health (NIH).

"Specifically, by her own admission, Ms. Wanchick engaged in research misconduct by *fabricating information* in the electronic database purportedly collected from 150 individuals about their willingness to sign up to be an organ donor at the time they obtained a driver's license. Ms. Wanchick also admitted to *fabricating the information* on several survey instruments. The study at issue was entitled 'Community Based Intervention to Enhance Signing of Organ Donor Cards.'

ORI acknowledges Ms. Wanchick's cooperation and assistance in completing its oversight review and resolution of this matter.

Ms. Wanchick has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on June 5, 2009:

(1) To [sic] exclude herself from serving in any advisory capacity to PHS [Public Health Service], including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) that any institution that submits an application for PHS support for a research project on which the Respondent's [i.e., Wanchick's] participation is proposed or that uses the Respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the research integrity of the Respondent's research contribution. Respondent agrees to ensure that a copy of the supervisory plan also is submitted to ORI by the institution.

Respondent agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI" (74 Fed. Reg. 30094-30095,

June 24, the emphases are added; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090624c.html).

For more information, contact: John Dahlberg, Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Ste. 750, Rockville, MD 20852 at 240-453-8800.

- **Office of Research Integrity.** A finding of research misconduct has been made in the case of Judith M. Thomas, Ph.D., a former professor of surgery at the University of Alabama at Birmingham. The misconduct occurred in research supported by five different grants from the National Institutes of Health (NIH).

“The objective of the research was to test the effectiveness of different agents, such as Immunitoxin FN18-CRM9 or 15-deoxyspergualin (15-DSG), administered around the time of renal transplantation in non-human [sic] primates, in preventing rejection of the transplanted kidney. To determine whether or not the transplanted kidney was functioning (able to sustain life) after the immunomodulating therapy, the animals were to have both of their native kidneys removed at or shortly after the time of transplant, so that their survival would depend solely on the viability of the transplanted kidney. It was postulated that the use of immunomodulating agents would increase tolerance of the host animal to the grafted kidney and thus eliminate the necessity for chronic administration of immunosuppressive medications commonly required to prevent rejection in renal transplant recipients. Failure to remove both native kidneys would render it impossible to assess the effectiveness of the immunomodulating treatment, *and could give totally misleading results, suggesting that the treatment worked while in fact survival was due entirely to the remaining native kidney.*”

PHS found that Respondent engaged in scientific misconduct by falsifying reports of research results in NIH-supported experiments with non-human [sic] primate (NHP) renal allograft recipients in 15 publications and in progress reports in two NIH research grant applications. Specifically:

A. Respondent falsely reported in 15 publications that NHP renal allograft recipients had received bilateral nephrectomies of their native kidneys, while in fact many of the animals retained an intrinsic kidney

Dr. Thomas accepted responsibility for the reporting described above, but denied that she intentionally committed research misconduct. The settlement is not an admission of liability on the part of the Respondent.

Dr. Thomas has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of ten (10) years, beginning on May 5, 2009:

(1) To [sic] exclude herself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as ‘covered transactions’ and defined by 2 CFR parts 180 and 376; and

(2) To exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant” (74 Fed. Reg. 31955-31957 at pp. 31955-39156, July 6, emphasis added; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090706c.html).

For more information, contact: John Dahlberg, Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852 at 240-453-8800.

- **Office of Research Integrity.** A finding of research misconduct has been made in the case of Juan Luis R. Contreras, M.D., an assistant professor of surgery at the University of Alabama at Birmingham and a coauthor on several publications with Dr. Thomas (see preceding item on research misconduct). The misconduct occurred in research supported by five different grants from the National Institutes of Health (NIH).

“PHS found that Respondent engaged in scientific misconduct by *falsifying in seven publications reports of research results* in NIH-supported experiments with non-human [sic] primate (NHP) renal allograft recipients” (74 Fed. Reg. 32167-32168 at p. 32168, July 7, emphasis added; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090707c.html).

For more information, contact: John Dahlberg, Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852 at 240-453-8800.

- **Secretary’s Advisory Committee on Human Research Protections.** The SACHRP scheduled its 20th meeting for July 21-22 in Arlington, Virginia.

“On July 21, 2009, the Committee will discuss a summary of comments from the recent OHRP [Office for Human Research Protections]-issued advance notice of proposed rulemaking on *institutional review board (IRB) accountability*, as well as hear a summary of Clinical and Translational Science Awards pediatric research issues. SACHRP will also spend time focusing on long-range future planning regarding *new subcommittees and areas of focus*. The day will conclude with a panel discussion addressing the question of *how to evaluate IRB effectiveness*.”

On July 22, 2009, the Committee will hear a report from the Subpart A Subcommittee focusing on *issues surrounding consent for future use of specimens or data* SACHRP will then hear a presentation of the recent National Academy of Sciences report entitled, ‘*Conflict of Interest in Medical Research, Education, and Practice*,’ followed by a panel discussion” (74 Fed. Reg. 31957, July 6, emphases added; on the Web via http://www.access.gpo.gov/su_docs/fedreg/a090706c.html).

The next SACHRP meeting is scheduled for October 27-28. For details, contact: Julia Gorey, J.D., Executive Director, Secretary’s Advisory Committee on Human Research Protections, HHS, 1101 Wootton Parkway, Ste. 200, Rockville, MD 20852 at 240-453-8141, or fax to 240-453-6909, or send e-mail to sachrp@hhs.gov, or see their Web site at <http://www.hhs.gov/ohrp/sachrp/>. ©

Compliance Conferences & Courses

By Kathleen K. Maloney, M.Ed., Associate Editor

HRR's favorites are **ALL IN BLUE**

- **August 6-7, 2009**, in San Diego, California: **"Monitoring Clinical Drug Studies -- Advanced."** This seminar will be offered by the Barnett International Conference Group. The topics will include: a review of FDA and ICH guidelines; reporting of adverse events; FDA regulatory authority and enforcement; and detecting fraudulent data and research misconduct. Contact: Barnett Educational Services, 5870 Trinity Parkway, Ste. 600, Centreville, VA 20120 at 800-953-3398, or fax to 703-543-3084, or send e-mail to customer.service@parexel.com, or see their Web site at www.barnettinternational.com.

- **September 11, 2009**, in New York, New York: **"On the Legal and Ethical Frontline."** This Research Community Forum will be sponsored by the Office for Human Research Protections (OHRP), with the City University of New York (CUNY), Columbia University, and Stony Brook University. The meetings will be held at the Graduate Center of CUNY. These educational events are designed to: (1) provide regulatory interpretation of the federal regulations on the protection of human subjects (see 45 CFR 46); (2) examine the special protections for vulnerable subject populations (e.g., children, women, prisoners); (3) address the responsibilities of the various parties involved in human subjects research; and (4) discuss the application of ethical principles and guidelines for the protection of human research subjects. Contact: Patricia A. MacCubbin, M.S., Executive Director of Research Conduct, Special Advisor to the Vice Chancellor for Research, CUNY, 535 East 80th Street, New York, New York 10075 at 212-794-5476, or send a fax to 212-794-5378, or send an e-mail to Patricia.MacCubbin@mail.cuny.edu.

- **September 14-15, 2009**, in Costa Mesa, California: **"Maximizing Global Patient Recruitment and Retention."** This course will be presented by The Center for Professional Innovation & Education, with the meetings to be held at The Hilton Hotel, Orange County. The topics will include: barriers to patient recruitment in various countries; special regulations in different countries; unique strategies to recruit human subjects in different cultures; and written recruitment documents. Contact: Conference Coordinator, The Center for Professional Innovation & Education, 992 Old Eagle School Road, Suite 913, Wayne, PA 19087 at (610) 688-1708.

- **September 14-15, 2009**, in Boston, Massachusetts: **"Good Clinical Practices for Pediatric Clinical Trials."** This seminar will be offered by the Barnett International Conference Group. The topics will include: special human subject protections for children; pediatric consents and clinical trials; ethics and assignment of risk; research misconduct and fraud; FDA regulations; recruiting pediatric patients; and working with parents. Contact: Barnett Educational Services, 5870 Trinity Parkway, Suite 600, Centreville, VA 20120 at 800-953-3398.

- **September 14-18, 2009**, in Washington, D.C.: **"2009 PDA/FDA Joint Regulatory Conference."** This conference will be presented by the PDA (Parenteral Drug Association) and the Food and Drug Administration (FDA). The topics will include: FDA guidances and initiatives; case studies of FDA audits and investigations; FDA rules on postmarketing surveillance for drugs; and the role of the Drug Safety Oversight Board (DSB).

Contact: PDA Conference Registrar, PDA Global Headquarters, 3 Bethesda Metro Center, Bethesda, MD 20814 at 301-656-5900, or send e-mail to info@pda.org.

- **September 15-16, 2009**, in Chicago, Illinois: **"Adverse Events -- Managing and Reporting for Pharmaceuticals."** This course will be offered by the Barnett International Conference Group. The topics will include: an overview of pharmacovigilance and related FDA regulations; definitions and levels of seriousness for adverse events; protection of human research subjects; IND safety reporting; international requirements; and HIPAA privacy issues. Contact: Barnett Educational Services, 5870 Trinity Parkway, Suite 600, Centreville, VA 20120 at 800-953-3398, or fax to 703-543-3084.

- **September 16-17, 2009**, in Portland, Oregon: **"5th Annual Three 'I's' Conference on IACUC-IBC-IRB Harmonization: Investigation, Institutional Committees, & Innovation."** This conference will be presented by the Massachusetts Society for Medical Research, Inc. (MSMR) and The Northwest Association for Biomedical Research. The topics will include: IACUC, IBC, and IRB connections--from bench to bedside; translational research; regulatory compliance; HIPAA updates; multicenter clinical trials; the difference between unanticipated problems and adverse events; and issues in common among the three types of institutional review committees. Contact: Massachusetts Society for Medical Research, 73 Princeton Street, Suite 311, North Chelmsford, MA 01863 at 978-251-1556, or fax to 978-251-7683, or e-mail to contact@msmr.org, or see their Web site at www.msmr.org. (*Rescheduled to 9/22-9/23/2010*)

- **September 21, 2009**, in Cambridge, Massachusetts: **"IRB 101."** This conference will be presented by Public Responsibility in Medicine & Research (PRIM&R), with the meetings to be held at The Hyatt Regency Cambridge. The topics will include: the history of the development of the federally mandated IRB system in the U.S.; ethical principles underlying the conduct of research with human subjects; an overview of the federal regulations governing the operation of IRBs; and case studies. Contact: PRIM&R, Ste. 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.

- **September 22, 2009**, in Cambridge, Massachusetts: **"IBC Basics: An Introduction to the NIH Guidelines and the Oversight of Recombinant DNA Research."** This program will be presented by Public Responsibility in Medicine & Research (PRIM&R). The topics will include: the history, function, and administration of Institutional Biosafety Committees (IBCs); the relationship between IBCs and Institutional Review Boards (IRBs); case studies; and the content of the NIH Guidelines for Research Involving Recombinant DNA Molecules. Contact: 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.

- **September 22-23, 2009**, in Cambridge, Massachusetts: **"IRB Administrator 101."** This program will be presented by Public Responsibility in Medicine & Research (PRIM&R).

The topics will include how to: advise principal investigators, research staff, IRB chairs and members, and institutional officials; manage protocol review; handle recordkeeping and reporting; deal with allegations and complaints; serve liaison functions; provide or oversee initial and continuing education; conduct quality improvement and assurance reviews; and coordinate off-site administrative agreements on human subjects studies. Contact: Program Coordinator, PRIM&R/ARENA, Ste. 202, 126 Brookline Avenue, Boston, MA 02215 at 617-423-4112, or fax to 617-423-1185, or send an e-mail to info@primr.org or info@arena.org, or see their Web site at www.primr.org.

- **September 24-25, 2009**, in San Diego, California: “Adverse Events: Managing and Reporting for Medical Devices.” This seminar will be offered by the Barnett International Conference Group. The topics will include: an overview of FDA regulations on developing medical devices; definitions and levels of seriousness for adverse events; protection of human research subjects; Investigational Device Exemption (IDE) safety reporting; international requirements; and HIPAA privacy issues. Contact: Barnett Educational Services, 5870 Trinity Parkway, Suite 600, Centreville, VA 20120 at 800-953-3398, or fax to 703-543-3084, or send e-mail to customer.service@parexel.com, or see their Web site at www.barnettinternational.com.

- **September 25-27, 2009**, in Nashville, Tennessee: “18th Annual SoCRA Conference.” This annual conference of the Society of Clinical Research Associates (SoCRA) will be held at a hotel to be announced. The topics will be announced, but we note that the topics typically cover numerous areas related to human subjects protection. Contact: Conference Registrar, SoCRA, 530 West Butler Avenue, Chalfont, PA 18914 at 800-762-7292, or fax to 215-822-8633, or send an e-mail to Office@SoCRA.org.

- **September 29-30, 2009**, in Philadelphia, Pennsylvania: “Patient Recruitment and Retention.” This seminar will be offered by the Barnett International Conference Group. The topics will include: principles of successful human research subject recruitment; and how to build positive relationships with consumers and participants in clinical trials. Contact: Barnett Educational Services, 5870 Trinity Parkway, Suite 600, Centreville, VA 20120 at 800-953-3398, or fax to 703-543-3084.

- **October 15-16, 2009**, in Philadelphia, Pennsylvania: “Clinical Research Monitoring Workshop for Site Coordinators, Monitors, and Auditors.” This course will be presented by the Society of Clinical Research Associates (SoCRA), with the meetings to be held at the Radisson Plaza Warwick Hotel. The topics to be covered will include: the 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; proactive study management; informed consent and IRB oversight; and ways to improve the efficiency and organization of clinical research monitoring. Contact: Conference Registrar, SoCRA, 530 West Butler Avenue, Chalfont, PA 18914 at (800) 762-7292, or fax to (215) 822-8633, or send e-mail to Office@SoCRA.org, or see their Web site at www.SoCRA.org.

- **October 21-22, 2009**, in Pittsburgh, Pennsylvania: “FDA Clinical Trial Requirements, Regulations, Compliance, and GCP Conference.” This conference will be presented by the Society of Clinical Research Associates (SoCRA), with the meetings to be held at the Renaissance Hotel Seattle. The topics will include: informed consent; how FDA performs inspections of clinical investigators; the ethics of clinical research related to patient treatment; medical and reg-

ulatory components of adverse event reporting; fraud in clinical research; the duties and responsibilities of Institutional Review Boards (IRBs); informed consent requirements; what the FDA expects of clinical trials; and related areas. Contact: Conference Registrar, SoCRA, 530 West Butler Avenue, Chalfont, PA 18914 at (800) 762-7292, or fax to (215) 822-8633, or send e-mail to Office@SoCRA.org, or see their Web site at www.SoCRA.org.

- **November 9-13, 2009**, in St. Louis, Missouri: “Clinical Science Course for Clinical Research Professionals.” This workshop will be presented by the Society of Clinical Research Associates (SoCRA), with the meetings to be held at the Millennium Hotel St. Louis. This is a two-module course which is offered by SoCRA. Module 1 includes: Institutional Review Board (IRB) guidelines; informed consent; Investigational New Drug (IND) and New Drug Application (NDA) regulations; preparing for Food and Drug Administration (FDA) inspections; ethical issues in clinical trials; clinical pharmacology and adverse event reporting; and related areas. Module 2 addresses basic science issues (cell biology, statistics, etc.), genetics, and ethical issues in clinical trials. Contact: Conference Registrar, SoCRA, 530 West Butler Avenue, Chalfont, PA 18914 at 800-762-7292, or fax to 215-822-8633, or send an e-mail to Office@SoCRA.org, or see their Web site at www.SoCRA.org.

Special Note: The following annual Public Responsibility in Medicine and Research (PRIM&R) 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 being offered after more than 30 years ... *they’re superb*. 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.

Special Benefit: Due to the partnership between the Boston University School of Medicine and PRIM&R, attendance at several of the preconference workshops and the conference itself have been approved by the Accreditation Council for Continuing Medical Education (ACCME) for AMA PRA Category I Credit(s) for physicians. Contact PRIM&R for details.

Location and Contact: All sessions will be held at The Gaylord Opryland Resort & Convention Center, 2800 Opryland Drive, Nashville, TN 37214 at 615-889-1000. Contact: PRIM&R, Suite 202, 126 Brookline Avenue, Boston, MA 02215 at 617-423-4112, or send a fax to 617-423-1185, or send e-mail to info@primr.org, or see their Web site at www.primr.org.

- **November 13, 2009**, in Nashville, Tennessee: “Institutional Review Board (IRB) 101 -- Biomedical Research.” This 1-day workshop will include: history, ethical principles, and current challenges; overview of federal regulations on the operations of IRBs; and case studies.

- **November 13, 2009**, in Nashville, Tennessee: “Institutional Review Board (IRB) 101 -- Social, Behavioral, and Educational.” This 1-day workshop will include the same topics as the biomedical research workshop, but in the context of social, behavioral, and educational research rather than biomedical research.

- **November 13, 2009**, in Nashville, Tennessee: “Advanced

Research Ethics.” This 1-day workshop will include: data on informed consent; research with children and adolescents; risk/benefit assessment; emergency research; coercion, undue inducement, and payment; and paternalism.

- November 13, 2009, in Nashville, Tennessee: “Hot Topics for Institutional Officials.” This 1-day workshop will include: conflict of interest; collaborative agreements for IRB reviews; research with embryonic stem cells; the Association for the Accreditation of Human Research Protection Programs (or AAHRPP) updates and accreditation standards; thorny issues of importance to institutional officials; international research; current legal issues confronting institutional officials; and a conversation with the Office for Human Research Protections (OHRP).

- November 13, 2009, in Nashville, Tennessee: “Institutional Review Board (IRB) 201 -- An In-depth Analysis of the Criteria for Review.” This 1-day workshop will include: overview of ethics and regulations; criterion 1 -- risks to participants are minimized; criterion 2 -- risks are reasonable in relation to anticipated benefits; criterion 3 -- selection is equitable; criterion 4 -- informed consent will be sought in accordance with and to the extent required by regulations; criterion 5 -- informed consent will be documented in accordance with and to the extent required by the regulations; criterion 6 -- research plan makes adequate provisions for monitoring safety; criterion 7 -- adequate provisions to protect privacy and maintaining confidentiality; criterion 8 -- additional safeguards for participants likely to be vulnerable to coercion or undue influence; and what it takes to be a good IRB member, including conflict of interest.

- November 13, 2009, in Nashville, Tennessee: “The Buck Starts & Stops Here -- Investigator Responsibilities for the Ethical Conduct of, and Protection of Human Subjects in, Research.” This 1-day workshop will include: what every researcher needs to know to design and run safe, ethical, and effective studies; how to work with IRBs; informed consent process, conference, and form; financial and nonfinancial conflicts of interest; recruitment and retention of human subjects; and what to report to IRBs, to the FDA, and to the subjects.

- November 13, 2009, in Nashville, Tennessee: “QA/QI 101 -- Fundamentals of Quality Assurance and Improvement in Human Subjects Research.” This 1-day workshop will include: explanation of QA/QI programs; communicating with the research community; QA/QI program tools and templates; and case studies.

- November 13, 2009, in Nashville, Tennessee: “Strategies for Successful International Research-- Lessons From Around the Globe.” This 1-day workshop will include: applying key ethical principles in different cultures and settings; multinational research challenges; research and therapeutic development; and translating regional experiences into best practices.

- November 13, 2009, in Nashville, Tennessee: “What Does It Mean to Represent the Community? A Primer on Community Participation in Research.” This 1-day workshop will include: the role and power of community involve-

ment in research; the history of abuses in human subjects research; the ethical principles of Belmont; the federal IRB regulations; the HIPAA Privacy Rule and research; and the role of the nonscientist in reviewing scientific protocols.

- November 13, 2009, in Nashville, Tennessee: “Human Genetics Research -- We Love the Knowledge, How We Fear the Data!” This 1-day workshop will include: genetics 101 -- science, terminology, and practical knowledge; specimen banking -- basic elements, regulatory oversight, and informed consent issues; and case studies.

- November 14-16, 2009, in Nashville, Tennessee: “2009 Advancing Ethical Research Compliance -- Navigating the Future Using the Belmont Compass.” The topics to be covered in the more than 140 panel presentations, workshops, and didactic sessions will include: stem cell research; hot topics in genetics, including GWAS; multicenter trials; the flexibility in the human subject protection regulations; tissue banking; regulatory compliance; quality improvement and quality assurance; international research; public health surveillance; informed consent; conflicts of interest; updates from the Secretary’s Advisory Committee on Human Research Protections (SACHRP); improving relationships between researchers and IRBs; how to incorporate best practices in research and in IRB operations; and much, much more.

- November 19-20, 2009, in Memphis, Tennessee: “Clinical Site Coordinator/Manager Workshop for Site Coordinators, Research Associates, Study Nurses, and Site Managers.” This conference will be presented by the Society of Clinical Research Associates (SoCRA), with the meetings to be held at the Peabody Memphis. The topics will include: elements of informed consent; the reporting requirements involving Institutional Review Boards (IRBs) and Institutional Ethics Committees (IECs); how to submit a protocol to an IRB; the ICH definitions of adverse events (AEs) and serious adverse events (SAEs); the rationale and issues surrounding the monitoring visit and the audit process from a site, a sponsor, and a regulatory perspective; and related areas. Contact: Conference Registrar, SoCRA, 530 West Butler Avenue, Chalfont, PA 18914 at (800) 762-7292, or fax to (215) 822-8633, or send an e-mail to Office@SoCRA.org, or see their Web site at www.SoCRA.org.

- December 3-4, 2009, in Miami Beach, Florida: “Clinical Investigator GCP & Trials Management Conference for Clinical Investigators and Key Research Staff.” Workshop to be presented by the Society of Clinical Research Associates (SoCRA), with the meetings to be held at the Holiday Inn Miami Beach. Topics include: the drug development process; investigator and site responsibilities; source documentation and research record management responsibilities; adverse event reporting; audits; the conduct of clinical trials; investigator-initiated research projects; protection of human research subjects; and how to monitor fraud and misconduct in human research. Contact: Conference Registrar, SoCRA, 530 West Butler Avenue, Chalfont, PA 18914 at (800) 762-7292, or fax to (215) 822-8633, or send e-mail to Office@SoCRA.org. ©

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Dennis M. Maloney, Ph.D., is the founding editor and publisher of the HUMAN RESEARCH REPORT. Dr. Maloney monitors a number of professional disciplines to keep readers up-to-date on human experimentation topics and events. As the author, coauthor, or editor of over 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*, was published in 1984 by Plenum Press in New York.

His Ph.D. in Experimental Psychology was granted (with honors) in 1973 by the University of Kansas. He then directed research and related projects during: two years at the Western Carolina Center in Morganton, NC; nine years at what is now known as Girls and Boys Town in Nebraska; two years at the Emergency Medical Services Council in Omaha, NE; six years at Creighton University; and then three years at the University of Nebraska-Lincoln. He is president of The Deem Corporation (a research consulting firm which he founded in 1984) and he directs the SolvAnon® service for solving research compliance and many other types of problems (e.g., see www.TellMyIRB.com), and Focus Surveys®.

Experienced in supervising both basic and applied research studies, he has faced the difficulties of constructing complete yet understandable informed consent documents and research protocols for the approval of 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 serving as its chairman, Dr. Maloney is familiar with the responsibilities and the challenges undertaken by IRBs which 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 workshop lectures. A member of many professional organizations, he has also served as the 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.