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Clinical Trials: Protecting Participants, Reducing Risk

CNA

VantagePoint[®]

A Risk Management Resource
for Hospitals and Health Systems

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Clinical trials are integral to innovation in the life sciences. As biotechnology has grown, human testing of the safety and efficacy of drugs and medical devices has developed into a \$20 billion industry.¹



An effective risk control strategy requires scrupulous oversight of the relationship with study participants, investigators, IRB members and sponsor companies.

The liability exposure associated with clinical trials conducted at hospitals and other health-care institutions has increased as well. According to a Jury Verdict Research survey of the period 1995-2005, half the payouts in single-claimant biotechnology cases exceeded \$1 million, with a mean award of \$3.1 million. One claimant was awarded \$43 million. Common allegations include bodily injury, failure to warn and conflicts of interest among sponsor companies, investigators and healthcare organizations. In addition, more creative legal theories of therapeutic misconduct and harm to self-dignity are being asserted.²

Despite the many well-publicized cases, the highly competitive nature of clinical research may lead investigators and institutional review boards (IRBs) to subordinate risk management considerations to other priorities. To properly protect themselves, administrators of healthcare organizations involved in clinical testing must be aware of the liability exposures that exist at every stage of the product development and marketing process. These include professional liability, product liability, regulatory sanctions, civil penalties and even criminal prosecution.

An effective risk control strategy requires scrupulous internal oversight of your organization's relationship with study participants, investigators, IRB members and sponsor companies. It also involves securing dual-coverage insurance that can protect your organization against both professional and product liability claims. This edition of *Vantage Point*[®] presents a variety of measures to help you identify and reduce the risks associated with clinical trials, and to access the resources available from agencies and organizations that promote research safety.

Regulatory and Liability Considerations

Due to the level of potential risk posed to subjects and consumers by clinical trials of drugs and medical devices, human research is highly regulated by the U.S. Food and Drug Administration (FDA) and other federal agencies. Drug trials must conform to the requirements of 21 *CFR Part 312* addressing investigational new drug applications, while medical device trials are governed primarily by the investigational device exemption under 21 *CFR Part 812*.

1 Baker, D. "The Benefits and Savings from Publicly-Funded Clinical Trials of Prescription Drugs." Washington, D.C.: Center for Economic and Policy Research, 2008. Available at http://www.cepr.net/documents/publications/clinical_trials_2008_03.pdf.

2 Goudsmit, F. et al. "Global Perspectives on the Life Sciences Industry." *The Journal of BioLaw & Business*, 2006. Volume 9:3. Abstract available at <http://www.biolaawbusiness.com/vol9num3.asp#1>.

Hospitals and academic institutions involved in clinical trials must recognize both the legal and ethical responsibilities owed to participants and sponsor companies. This involves ensuring that clinical study protocols incorporate government regulations and established industry best practices regarding

- review and approval processes
- IRB accreditation and compliance with explicit standards, operating procedures and monitoring protocols
- competence of investigators as evidenced by academic and professional qualifications, experience and training
- training of investigators in research conduct and IRB requirements
- ability of research facilities to support planned activities
- management of potential adverse outcomes
- mechanisms to handle research-related complaints and misconduct
- control of access to data and findings
- accounting of research-generated income

Noncompliance with government standards and best practices may translate into significant liability. Allegations of wrongdoing may arise in various stages of the testing process, as seen below:

CLINICAL CARE	RESEARCH DESIGN	PRODUCT LIABILITY	MARKETING
<ul style="list-style-type: none"> ▪ Negligent harm by employees to human subjects ▪ Vicarious liability for negligent acts of contracted investigators or employed professionals ▪ Violation of the right to individual autonomy and to be free of or refuse unwanted treatment ▪ Failure to adequately inform human subjects of risks, benefits and alternatives to treatment 	<ul style="list-style-type: none"> ▪ Faulty design and protocol development ▪ Failure to undertake comprehensive scientific review ▪ Breach of ethical duty to maintain dignity, rights and safety of human participants ▪ Intellectual property infringement, fabrication or falsification in proposing, conducting or reporting research 	<ul style="list-style-type: none"> ▪ Strict liability for defective products ▪ Defects in design, production, marketing and promotion practices ▪ Noncompliance with packaging and labeling regulations ▪ Financial loss arising from a product recall or other type of business interruption 	<ul style="list-style-type: none"> ▪ Fraud involving misrepresentation of defective drugs or other products ▪ Civil/criminal complaints stemming from Medicaid and Medicare fraud ▪ Sanctions for noncompliance with federal and state regulations regarding promotion of clinical trials ▪ Deceptive advertising, e.g., misrepresentations regarding potential for clinical improvement

While insurance coverage can minimize some of the consequences of clinical research error (see "Selecting the Appropriate Insurance Coverage," page 5), sound risk management strategies are essential to protect participants and integrity of data. The following guidelines, based on government and professional association sources, can serve as a starting point in evaluating and refining a clinical trials risk management program.

Institutional Review Boards

All research involving human subjects must be reviewed and approved by the institutional review board (IRB) of the hospital or healthcare organization. An IRB is a body authorized by federal regulations to evaluate a clinical research study. Failure of the IRB to ensure high ethical and safety standards may lead to litigation and other undesirable outcomes. For this reason, organizations must implement an effective IRB member selection process guided by clear criteria. The board should include not only members with backgrounds in medicine and science, but also community representatives who can offer a non-institutional perspective on whether the research protocol adequately respects and protects the rights, dignity and well-being of participants.

By appointing one or more lay members to the IRB, organizations can lessen the tendency to recommend without due consideration protocols developed by highly regarded physicians. An increasing number of hospitals and academic institutions seek input from external or independent review boards to ensure that their own IRBs are meeting the standards set forth by the Office for Human Research Protections of the U.S. Department of Health and Human Services.

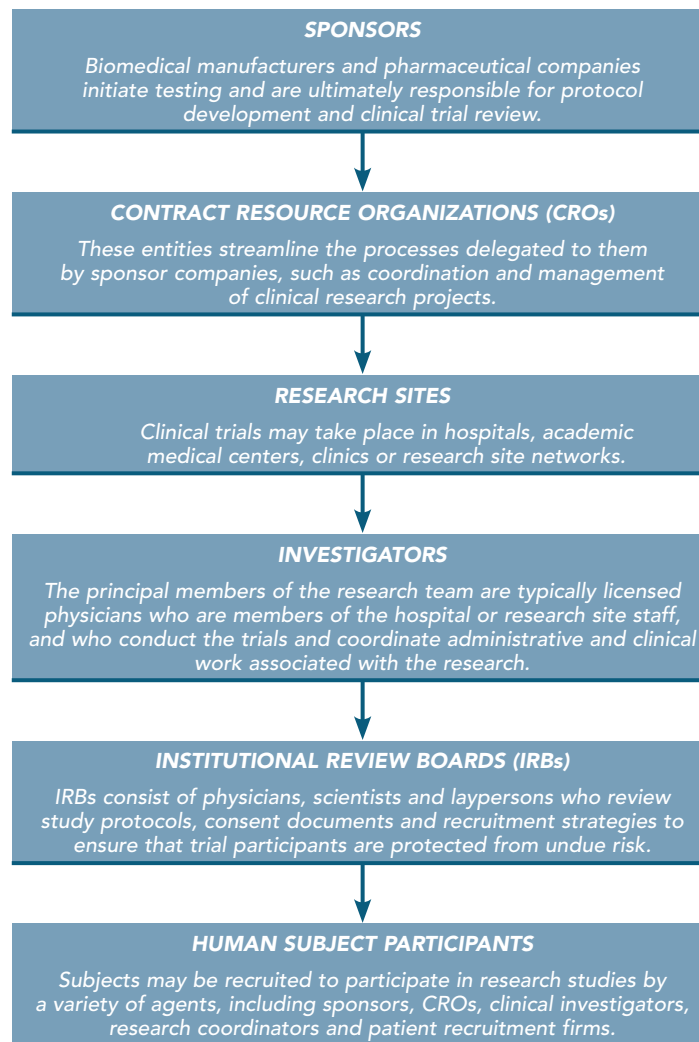
IRBs should be accredited by a recognized professional body, such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Board members should demonstrate a commitment to thoroughly review all study protocols, focusing on the following key elements:

- **study design**, including target population and risk/benefit ratios
- **scientific principles and methods** relied upon to produce and analyze data
- **social and scientific significance** of the trial
- **protective measures** for study participants
- **competence and qualifications** of the research team
- **adequacy of the hospital's resources** to conduct the study
- **anticipated possible outcomes** of the research effort
- **indications for terminating the study** if its continuation poses too great a risk for participants

As an additional safety measure, all modifications to a protocol, informed consent form or recruitment plan made by an IRB should be reviewed and approved by the sponsor company. To learn more about established quality standards for IRBs and recommended protections for participants, visit the AAHRPP Web site at <http://www.aahrpp.org/www.aspx?PageID=27>.

Selecting the Appropriate Insurance Coverage

The research process includes several parties, all of whom are critical to the overall success of a clinical trial and have their own risk exposures, as illustrated in the following diagram:



The increase in life-sciences litigation makes it incumbent upon hospitals and academic medical centers to review both the nature of their relationships with all of these entities, and the adequacy of their insurance coverage. By selecting the appropriate insurance coverage, you can protect against potentially crippling losses.

The Advanced Medical Technology business unit of CNA HealthPro offers insurance products designed to cover both professional liability and products-work hazard liability. This insurance coverage can help you address exposures to

- claims for bodily injury due to negligent or deficient product testing
- claims for bodily injury alleging a defect in the design of the protocol
- claims for damages to the sponsor company arising out of errors made while conducting the trial or collecting data

Liability insurance for clinical trials helps reduce your organization's exposure and demonstrates prudent financial management and accountability in an increasingly competitive marketplace. To speak to an Advanced Medical Technology representative about your coverage needs, call CNA HealthPro at 1-888-600-4776.

Principal Investigators

Organizations that host research studies must scrutinize the qualifications and training of the principal investigator (PI) and thoroughly document the evaluation process. Ensure that screening of PI candidates is based upon written criteria and focuses on the following competence and reliability indicators:

- **formal education**, training and certification
- **employment relationships**, if any, with the hosting hospital or institution
- **workload demand assessment** to ensure PIs can prioritize and accomplish necessary goals
- **expertise and experience** working with the specific patient group
- **past allegations** of regulatory noncompliance, violations or fraud
- **relationship with the sponsor company** (i.e., whether the prospective PI has a business association with the sponsor company or is acting as the trial sponsor)
- **insurance coverage** and malpractice history

Participants in a clinical trial headed by their personal physician may feel betrayed if an adverse event occurs or expectations are not met, and consequently decide to pursue legal recourse. Therefore, organizations hosting research should examine any existing professional relationship between the PI and human subjects and remain alert to the PI's methods of recruitment. Before authorizing the inclusion of any current patients of the PI in a study, thoroughly document their eligibility. Also, as the enrollment deadline nears, review any special incentives offered to the PI by the sponsor organization or its delegated clinical research organization, as these may lead to questionable recruitment tactics.

While PIs must be paid for their time and service, potential conflicts arise when sponsor companies compensate PIs by giving them a financial stake in the product's success. Although not prohibited under current law, these arrangements raise questions about participant safety, data integrity and medical ethics. Organizations are advised to err on the side of caution and disclose to regulatory bodies and study participants relevant information regarding compensation arrangements beyond what is minimally required.

Hospitals and academic medical centers are further encouraged to minimize their PI-related exposures by utilizing an independent data safety committee to monitor study integrity. The oversight functions of such a committee are distinct from and independent of IRB activities and approvals. For additional measures designed to protect organizations in their relationship to sponsor companies and principal investigators, see "Sponsor Agreements: A Key Measure to Minimize Risk," page 7.

Human Subject Protections

Finding suitable subjects for clinical trials is a major challenge for sponsor companies, who face expensive delays in product approval if recruitment problems arise. Specialized patient recruitment firms have emerged to expedite the process. However, serious consequences may result when a subject who should not have been enrolled in the study experiences an adverse event on your organization's premises.

Sponsor Agreements: A Key Measure to Minimize Risk

SIDEBAR 2

Depending on their nature, written agreements between the sponsor company and the research site may either minimize or exacerbate potential liability. Your legal counsel should review any additional agreements between the principal investigator (PI) and the sponsor company, especially when the PI is a faculty or staff member of your hospital or healthcare facility. Such agreements may expose your organizations to claims based upon the PI's wrongdoing, third-party actions or other unpredictable financial obligations.

The business agreement between the sponsor and your organization should be fully executed before the clinical trial's protocol is submitted to the institutional review board (IRB), as final approval of the protocol is contingent upon execution of the agreement. Before signing any agreements, have your legal counsel review them with the following contract guidelines in mind:

Conflict disclosure. *The written agreement should require PIs to fully disclose any financial interest in a sponsor company's research. Additionally, if the trial is being administered by a contracted research organization (CRO), and an entity other than the manufacturer is a party to the agreement, both the sponsor company and the CRO must disclose any financial interest in the research to federal and state oversight bodies and trial participants. Finally, the IRB must seek to identify any potential conflicts of interest and ensure that the informed consent form discloses such conflicts to potential subjects.*

Reimbursement for injury. *The agreement should make one party responsible for reimbursing reasonable medical costs due to injuries directly incurred from participation in the study. Sponsor companies may attempt to reduce costs by inserting contract language that offers to reimburse participants for treatment after they have billed their insurance company. Such boilerplate inclusions rarely provide adequate protection for either party. Responsibility for research-related injury costs should be assigned to the sponsor or the research site, with reimbursement limited to reasonable medical expenses. Additionally, stipulate that willingness to defray medical expenses shall not be deemed an admission of fault or liability by the sponsor organizations, its CRO or the research site.*

Recovery of costs. *The contract should delineate whether the trial will be supported, in whole or in part, by funds from grants, foundations, sponsorships or donations. In addition, consider establishing a clinical trial fund from which associated costs are charged, with controls to ensure that these funds are not commingled with other accounts. Finally, create a payment schedule, meticulously record charges submitted to medical insurance plans, and abide by state and federal regulations governing such charges.*

IRB approval. *The agreement should state that all protocols and supporting documents for testing a sponsor's drug or device will be reviewed and approved by your IRB. Include a schedule for the PI to report to the IRB on trial progress, taking into account audits and other key points during the research.*

Any changes to an approved agreement should be authorized only after review by legal counsel, as modifications may affect liability coverage.

Advertising for clinical trial participants by investigators, hospitals and other research sites should never target vulnerable individuals for risky research. Federal regulation dictates that these advertisements must be approved by the IRB. The following strategies for recruitment can help minimize the potential for harm to subjects, and reduce liability associated with participants' false or inflated expectations for clinical improvement:

- Clearly define the population from which trial participants will be recruited.
- Honor confidentiality provisions for protected health information when searching disease registries, school records or other databases for potential subjects. (See "The HIPAA Privacy Rule: Protected Health Information and Clinical Trials," page 11.)
- Delineate exclusionary criteria, basing them on fair and reasonable indicators – e.g., evidence of advanced disease.
- Select participants who seem willing and able to complete the study, which may take many months.
- Avoid making promises or understating the experimental nature of clinical trials in advertisements and recruitment materials.
- Disclose fees paid to investigators for successfully recruiting subjects.
- Inform existing and prospective participants of newly discovered risks or benefits as the trial progresses.
- Compensate subjects for their time and travel expenses at a level commensurate with, and no greater than, industry standards.
- Allow participants to withdraw from the clinical trial at any time, and do not pressure them to remain.

Physician investigators are sometimes awarded bonuses by sponsor companies for their recruiting success. In their effort to meet enrollment quotas, they may deviate from accepted standards and employ a more "hard sell" approach. Always review the agreements between PIs and sponsor companies, focusing on the bonus award structure and provisions regarding compliance with recruitment standards.

The Bioresearch Monitoring (BiMo) program is the FDA's primary mechanism for ensuring that human subjects are protected during clinical trials. Critics of the BiMo program argue that the FDA lacks the ability to accurately track and oversee human trials, and advocate for a central ethics organization to promote transparency and accountability in all aspects of clinical research.³ For information on BiMo efforts to audit sponsors, research sites, clinical investigators and IRBs, visit http://www.fda.gov/ora/compliance_ref/bimo/.

³ Rackoff, J., Kotwani, N. "Improving Protection of Trial Participants." *Genetic Engineering & Biotechnology News*, January 15, 2008. Volume 28:2. The article, which is posted online at http://www.genengnews.com/articles/chitem_print.aspx?aid=2327&chid=0, cites a September 2007 report from the U.S. Department of Health and Human Services Office of Inspector General that is sharply critical of the FDA's Bioresearch Monitoring program.

Informed Consent

Before enrolling in a clinical trial, participants must be thoroughly informed of the nature of the study and the risks involved, and sign a document indicating their consent. To protect the integrity of the process, the authors of study protocols are required to prepare the consent documents and secure IRB review and approval. Hospitals and other research sites should offer investigators, department heads, research administrators and clinical research staff extensive training on informed consent procedures.

According to the Office of Human Research Protections, research subjects must be informed prior to enrollment that the trial involves research, and that their participation is voluntary. In addition, participants must be advised that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled. Participants also should be provided the following information in writing:

- purpose of the research and its expected duration
- description of test procedures, including any experimental aspects
- material hazards and potential complications
- foreseeable risks and/or discomfort associated with the research
- health benefits that may reasonably be expected from the treatment
- likely effects of non-treatment on their health and well-being
- alternative procedures or other courses of treatment
- foreseeable consequences of withdrawing from the research project
- incentives for participation, including level of compensation
- confidentiality safeguards for records identifying the subject
- treatments available if injury occurs and compensation for related medical costs
- researchers' contact names and numbers for answers to subjects' questions about the research and their rights



Research subjects must be informed that the trial involves research, that participation is voluntary, and that refusal to participate involves no penalty or loss of benefits.

The PI should bear the responsibility for obtaining informed consent. If this function is delegated, organizations must verify that those who conduct the informed consent protocol possess the requisite skills. Any changes made by an IRB to consent forms must be reviewed and approved by the PI involved in the research, as well as the sponsor company.

These additional suggestions can help safeguard the consent process:

- **Never equate a clinical trial with routine healthcare**, and ensure that participants understand that they may receive no direct benefit from participation.
- **Provide information about the nature of the research** and allow time for one-on-one discussion and questions.
- **Offer participants general educational materials**, such as videos and interactive learning modules.
- **Assess prospective subjects' comprehension** of the nature, purpose and risks of the clinical trial.
- **Draft forms that are easy to understand**, i.e., targeted at an eighth-grade reading level.
- **Thoroughly document all educational efforts** and subjects' voluntary consent.
- **Refrain from exculpatory language in consent documentation** that would effectively waive or appear to waive any of the subject's legal rights, or release the investigator, sponsor, institution or its agents from liability for negligence.

The HIPAA Privacy Rule, promulgated under the Health Insurance Portability and Accountability Act of 1996, specifies that a covered entity may neither use nor disclose protected health information (PHI) for research purposes without advance patient authorization. Under the law, a “covered entity” is defined as a healthcare provider, plan or clearinghouse, and thus includes most investigators and facilities conducting research. While an IRB may grant a waiver of authorization under certain circumstances, research subjects typically must sign a written authorization form as a precondition to disclosure of PHI.

Authorization form elements. For convenience, federal regulations permit PHI authorization to be included within informed consent documentation. When research sites combine the two documents, then the IRB rather than the investigator becomes principally responsible for ensuring that the authorization complies with Privacy Rule requirements. This involves informing subjects in writing of the following facts:

- what personal information will be used in the study
- who will use or disclose this information
- to whom this information will be disclosed
- why the research may result in disclosure of PHI
- when the authorization expires (typically, at the end of the study)

Additionally, researchers must notify participants in writing that their right to access their PHI may be suspended during the study, and that their PHI may be re-disclosed for secondary research purposes. Finally, participants should be informed that participation in the study is conditional upon signing the authorization form.

Revocation. The form also must state that the patient has the right to revoke the authorization. Upon receipt of a written revocation, the investigator and research team must stop using and/or disclosing PHI, except for certain narrowly defined purposes, including the following:

- to account for a subject’s withdrawal from the research study
- to include in safety analyses when requesting permission from the FDA to market the device or drug being tested
- to aid in investigations of misconduct
- to report adverse events

No PHI collected after the date of revocation may be used for any purpose.

Recruitment practices. Before a clinical trial begins, investigators may review the PHI of their own patients without authorization to determine whether a patient may be eligible to participate in testing – but only if the Privacy Notice that patients signed at the outset of the physician-patient relationship informed them of the potential use of PHI for this purpose. If the Privacy Notice signed by patients did not inform them of this potential use or disclosure of PHI, then authorization must be obtained. Investigators who do not have a pre-existing relationship with prospective participants, and who conduct screening interviews that result in the recording of PHI, must obtain a written authorization. To protect patient privacy, any review of PHI at any time must be conducted on-site.

If an investigator asks a colleague to identify eligible patients for clinical trials, the investigator must verify, before sharing any PHI, that the referring physician has obtained either an authorization from the referred patient or a waiver for this purpose.

If your organization utilizes the services of a recruitment center, bear in mind that most such firms are not considered “covered entities” under the HIPAA Privacy Rule. However, to protect against a breach of confidentiality, federal regulations require sponsor companies and research sites to submit any advertising to the IRB for prior approval to ensure that recruitment procedures comply with the HIPAA Privacy Rule.

In addition, if the release of study data could have negative consequences to a participant due to the nature of the disease or condition, the study is eligible to receive a Certificate of Confidentiality from the National Institutes of Health. This is a legal document that protects both investigators and healthcare entities conducting research from being compelled to reveal information that could identify research participants.

Monitoring Adverse Events

Clinical trials seek to protect study participants while generating and recording sufficient data to support a firm conclusion about product safety and efficacy. To achieve these twin goals, researchers must adhere to numerous and complex regulations, especially regarding the recording and reporting of adverse events.⁴

Investigators must distinguish minor events from those subject to recording and reporting requirements. A consensus has developed that the following occurrences are reportable to the FDA, external IRBs and participating investigators:

- complications of the device/drug that affect the original prognosis
- worsening of an underlying condition related to use of the drug/device
- investigator-related events caused by lack of training
- treatment or device failure resulting in adverse consequences
- protocol violation or deviation by investigators or subjects
- failure to meet selection criteria
- failure to obtain informed consent

Adverse event data should be collected at predetermined intervals throughout the clinical trial and whenever an occurrence becomes known to an investigator or healthcare organization. To ensure that investigators and clinical research staff know how to complete adverse event forms in an accurate and thorough manner, provide examples of completed forms in training sessions.

Data-collection forms should include a list of possible adverse events, as well as spaces for the following information:

- study's name and identification number
- names of principal investigator and subject
- data being collected
- description or name of event
- date of event's onset and resolution
- intensity of injury
(e.g., potential disability, malignancy, congenital anomaly, danger to life, death)
- relationship to device or drug
(i.e., probable, possible, unrelated)
- required treatment
(i.e., outpatient, hospital stay, home care)

⁴ A comprehensive discussion of standards for recording and reporting data is beyond the scope of this article. For information, consult Rozovsky, F. and Adams, R. *Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance*. San Francisco: Jossey-Bass/Wiley, 2003.

Study protocols should link adverse event reporting systems to patient monitoring programs, including ongoing serum and urine tests, x-rays, electrocardiograms and other diagnostic measures. Protocols should include clear removal criteria to help investigators determine if a subject's worsening condition warrants withdrawal from the study.

Reporting programs also should include the following:

- input from expert advisory meetings
- documentation retention practices and security provisions
- product tracking systems and recall measures
- subject withdrawal policies
- procedures for responding to patient and physician complaints
- mandated adverse occurrence reporting by the sponsor company's sales representatives, if they witness or hear of a potentially injurious incident

Human testing is indispensable to medical and scientific progress. However, failure to adhere strictly to regulations and clinical standards can endanger participants, corrupt data, undermine consumer trust, and create the potential for litigation and consequent financial loss. By focusing on protocol review, subject recruitment practices, informed consent procedures and adverse event monitoring, your organization can enhance participant safety and data integrity while reducing the level of risk for those involved in clinical trials.

Resources

Resource Organizations

- American Society for Healthcare Risk Management (ASHRM), at www.ashrm.org (See also the ASHRM *Risk Management Handbook for Health Care Organizations*, 5th edition, 2006, Volume 1, Chapter 7 and Volume 2, Chapter 5.)
- Applied Research Ethics National Association (ARENA), a membership organization associated with Public Responsibility in Medicine and Research (PRIM&R), <http://www.primr.org>
- Association for the Accreditation of Human Research Protection Programs, Inc.® (AAHRPP), www.aahrpp.org
- Association of Clinical Research Professionals (ACRP), www.acrpnet.org
- CenterWatchSM Clinical Trials Listing ServiceTM, www.centerwatch.com

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