



New WPP: Identification and Recruitment of Research Participants

The VCU IRB has adopted a new Written Policy and Procedure (WPP) to guide investigators and IRB reviewers regarding strategies for the identification and recruitment of research participants. The WPP can be found at [insert link to new WPP]. In finalizing this WPP, the IRB considered the very thoughtful feedback that many investigators provided on the draft policy.

Within this policy, VCU provides specific guidelines for using private identifiable information (including, but not limited to Protected Health Information) for the identification and recruitment of potential research participants.

What IS Covered by this new WPP:
This policy addresses investigator plans to identify, notify, and ultimately recruit research participants where:

1. Private identifiable information is collected or otherwise recorded by the investigator/research staff for the purpose of initiating future contact with prospective research participants *and*
2. The investigator has no prior permission from a prospective research participant to access his/her private identifiable information. (Note: From an IRB perspective, a signed HIPAA Notice of Privacy Practices does not constitute permission).

What IS NOT Covered by this new WPP: This policy does not apply to or limit research activities involving the identification or recruitment of prospective research participants from public lists or other non-confidential data sources. This policy also does not restrict feasibility determinations for research involving Protected Health Information (PHI). As a reminder: The VCU Department of Assurance Services has noted that feasibility determination practices should not involve removing any private information from the premises of the organization that is responsible for protecting the information.

For a complete copy of this policy, go to:

<http://www.research.vcu.edu/irb/wpp/flash/XII-4.htm>

Additional guidelines are in place regarding advertising and other recruitment matters. See:

1. [VCU IRB WPP XVII-2: Advertising for Subject Recruitment and Compensation Guidelines](#) *and*
2. [VCU IRB WPP XVII-9: Use of the Internet for Recruitment and/or Research Data Collection.](#)

This "Bulletin" is a quarterly electronic publication of the Office of Education and Compliance Oversight (OECO). For more information or to contribute to this bulletin, contact Lisa Ballance at lballanc@vcu.edu or Monika Markowitz, Ph.D. at msmarkow@vcu.edu.

Upcoming Educational Events (Use this link to access the on-line calendar)

- **Friday, April 24, 2009: Research Coordinator 4th Friday Lunch & Learn Seminar Series**; 12:00 noon—1:00 pm; Children's Pavilion—2017. Topic to be announced.
- **Friday, April 30, 2009: 5th Thursday for Human Research Protections**; 1:00 — 2:30 pm; Biotech I—Ball Conference Room. Topic to be announced.
- **Friday, May 22, 2009: Research Coordinator 4th Friday Lunch & Learn Seminar Series**; 12:00 noon—1:00 pm; Children's Pavilion—2017. Topic to be announced.

- **Friday, June 26, 2009: Research Coordinator 4th Friday Lunch & Learn Seminar Series**; 12:00 noon—1:00 pm; Children's Pavilion—2017. Topic to be announced.
- **Friday, July 24, 2009: Research Coordinator 4th Friday Lunch & Learn Seminar Series**; 12:00 noon—1:00 pm; Children's Pavilion—2017. Topic to be announced.

Accreditation News:

VCU is preparing to renew its accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The process is very similar to our original submission process almost 3 years ago. At this time, we have begun the re-accreditation process with a comprehensive self-assessment underway.

Accreditation benefits research organizations, participants, and the research enterprise as a whole. The accreditation process requires organizations to take a comprehensive look at their human research protection programs (HRPPs)—to identify and address any weaknesses and to build upon their strengths. The result is focused on developing a more cohesive HRPP, with the systems in place not only to protect research participants but also to advance research more efficiently and effectively.

AAHRPP looks at a programmatic approach to human research protections. There are 5 domains of evaluation: the institution, the research review unit, the investigators, sponsors, and research participants. VCU will be providing evidence that all of those areas receive comprehensive attention. AAHRPP will again be asking, during their site visit, to interview particular investigators, research coordinators, IRB members and staff, and including the University President, General Counsel, and a variety of Department Chairs. For more information visit: <http://www.aahrpp.org/www.aspx>

Recent News in Human Research

- **Medical Clinical Research Slows for Lack of Patients. Los Angeles Times, March 14, 2009** ~ " ...But the reluctance of Americans to participate in clinical trials has been a serious drag on medical research. Enrollment problems delay more than 70% of clinical trials from one to six months, according to a 2007 survey by CenterWatch, a Boston-based company that publishes information on clinical trials. In cancer care, less than 5% of patients enter clinical trials... "
- **Being a Research Subject a Lure in Hard Times, Modesto/Sacramento Bee, March 17, 2009** ~ " ...With the economy careening and millions uninsured, some doctors and researchers believe the lure of volunteering for medical research is growing -- and so are potential ethical pitfalls... "
- **Safety of Drug Trials Tested. A Government Sting Shows that Regulations May Be Failing. AARP Bulletin. March 19, 2009** ~ IRBs in the hot seat! " ...Coast Independent Review Board in Colorado Springs approved the study last November. But five months after approving the use of human subjects for the trial, Coast CEO Daniel Dueber says he sensed a problem when he was contacted recently by a congressional subcommittee and asked to testify about the gel trial... "

ref: Illuminata, Inc.