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# OHRP—VCU Conference

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## OHRP—VCU Regional Conference

Tuesday, Sept. 16, 2008

### *“Informed Consent and More: Improving Human Research Protections”*

Sheraton Richmond West

#### *Conference Description*

*The Belmont Report*, promulgated in 1978 by the national Commission for the Protection of Human Subjects, identifies three related principles intended to characterize the manner in which human subjects ought to be involved in research. They are: *Respect for Persons*; *Beneficence*; and *Justice*. The principle of *Respect for Persons* usually finds expression in the process by which human subjects consent to participate in research as subjects.

Tragically, some thirty years after the publication of *The Belmont Report*, contemporary studies suggest that informed consent is often elicited in a manner that manifests little respect for the dignity of volunteers who, for the sake of the common good, place themselves in the hands of research investigators.

The jargon used in virtually every institution – “consenting subjects” or “getting consents” -- betrays the fact that eliciting informed consent has often been reduced to the level of an action taken by a PI or a member of the research team to obtain a signature on a legal document in order to comply with the law. All too often “consenting” means little more than a halfhearted and misguided attempt to provide legal cover for investigators and for their institutions.

This conference is intended to identify shortcomings in the ways that informed consent is elicited, and to promote a mindset in which receiving permission from a subject to proceed with research is recognized as a privilege; and to endorse informed consent procedures conducted in the context of *Justice* and *Beneficence* that manifest profound respect for human dignity. Conference speakers include many VCU researchers and IRB members. Registration will be available mid May, 2008!

***For more information about this conference and opportunities to volunteer, please contact The Office of Education and Compliance Oversight 827-2157 or [mmarkow@vcu.edu](mailto:mmarkow@vcu.edu).***

***Save the Date***

***Tuesday, Sept. 16, 2008***

***8:00 a.m.—5:15 p.m.***

***(Registration and Breakfast***

***begin at 7:00a.m.)***

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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 Monika Markowitz, Ph.D., Director of the Office of Education and Compliance Oversight at 827-2157 or [mmarkow@vcu.edu](mailto:mmarkow@vcu.edu).

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

- **Thursday, May 29, 2008: 5th Thursday for Human Research Protection** 1:00 pm—2:30 pm; Ball Conference Room, Biotech 1: *"When Informed Consent in Research May Not Apply,"* Andrea Hastillo, MD, Chair, IRB Panel C, Internal Medicine, Division of Cardiology; Monika Markowitz, PhD, Director OECO; Joe Ornato, MD, Chair, Division of Emergency Medicine
- **Friday, June 21, 2008: Research Coordinator 4th Friday Lunch and Learn** 12:00 noon—1:00 pm; Children's Pavilion—2017. Topic to be announced.
- **Friday, July 25, 2008: Research Coordinator 4th Friday Lunch and Learn** 12:00 noon—1:00 pm; Children's Pavilion—2017. Topic to be announced.
- **Thursday, July 31, 2008: 5th Thursday for Human Research Protection** 1:00 pm—2:30 pm; Ball Conference Room, Biotech 1. Topic to be announced.
- **Friday, August 22, 2008: Research Coordinator 4th Friday Lunch & Learn Seminar Series;** 12:00 noon—1:00 pm; Children's Pavilion—2017. Topic to be announced.
- **Tuesday, September 16, 2008: OHRP—VCU Regional Conference;** 7:00 am—5:15 pm; Sheraton Richmond West. *"Informed Consent and More: Improving Human Research Protections"*

## **Selected Recent IRB Policy Changes:**

Use the hyperlinks to access the policy files directly—

[Click here](#) for a full, text-searchable, electronic set of VCU IRB written policies and procedures

<b>WPP</b>	<b>Title</b>	<b>Effective Date</b>
XVI-7	<a href="#">Control of Investigational Drugs, Devices, and Biologics</a>	4-15-08
XVI-2	<a href="#">Humanitarian Use Devices</a>	2-15-08
VI-2	<a href="#">Suspensions and Terminations of Previously Approved Research</a>	1-30-08
XVII-7	<a href="#">Evaluating Consent / Persons with Limited Decision-making Capacity</a>	1-30-08
VIII-7	<a href="#">Required Reporting of Unanticipated Problems Involving Risk</a>	1-15-08
IX-1	<a href="#">Principal Investigator Eligibility and Signed Statement of Responsibilities</a>	1-15-08
XVII-6	<a href="#">Involving Non-VCU Institutions in Human Subjects Research</a>	1-15-08
III-4	<a href="#">NCI Pediatric Central IRB</a>	12-1-07

## **Recent News in Human Research**

- [Report Claims Clinical Trials Miss Many Populations, Health Day, Apr 1, 2008](#) "A new analysis of the American clinical trial process suggests that the system for testing new drugs has routinely excluded or under-represented women, older people, minorities, disabled individuals and rural populations for decades..." [White Paper: Eliminating Disparities in Clinical Trials, EDICT Project, Baylor College of Medicine, Apr 2008](#) (pdf, full report freely available)
- [Patients' Data on Stolen Laptop. Identity Fraud Not Likely, NIH Says, Washington Post, Mar 24, 2008](#) (free one time registration required) "A government laptop computer containing sensitive medical information on 2,500 patients enrolled in a National Institutes of Health study was stolen in February, potentially exposing seven years' worth of clinical trial data, including names, medical diagnoses and details of the patients' heart scans. The information was not encrypted, in violation of the government's data-security policy..." [Information Security: Department of Health and Human Services Needs to Fully Implement Its Program, US Government Accountability Office \(GAO\), Feb 2008](#) (pdf)
- [Citing Ethics, Some Doctors Are Rejecting Industry Pay, New York Times, Apr 15, 2008](#) (free one time registration required) "With little fanfare, a small number of prominent academic scientists have made a decision that was until recently all but unheard of. They decided to stop accepting payments from food, drug and medical device companies..." "With little fanfare, a small number of prominent academic scientists have made a decision that was until recently all but unheard of. They decided to stop accepting payments from food, drug and medical device companies..."