



Human Research Protections Bulletin

Don't Forget to Check Online...
IRB News

Focusing on Privacy

One of the most basic criteria for IRB approval is that adequate provisions are in place for protecting the privacy and confidentiality of data related to research participants [45 CFR 46.111(a)(7) and 21 CFR 56.111 (a)(7).]

On November 16, 2007, Dr. Frank Macrina, VCU Vice President for Research, issued a written reminder to investigators and research staff regarding the protection of personal and identifiable data at all stages of research (from preparatory work through research data storage). This letter described research issues dealing with privacy standards and confidentiality standards and serves as a clear depiction of the requirements of the VCU IRB and institutional HIPAA standards.

This reminder, on the heels of data breaches at our institution and national events related to privacy and confidentiality, presents an opportunity for us all to think about all our research activities and issues of both 'privacy' and 'confidentiality.'

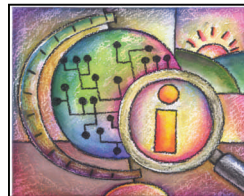
For the record: *Privacy* refers to persons and their interest in controlling the access of others to themselves. On the other hand, *confidentiality*, refers to the agreement between the investigator and participant in how data will be managed and used. While issues of confidentiality are often addressed within the consent process and also the IRB application (description of data security plans), privacy issues often crop up even before IRB approval is needed. Here are a couple of examples:

Do I have enough potential subjects for this study? A simple enough question! HIPAA regulations do cover this activity, though—and you will need to obtain pre-approval from the Compliance Services Department to use any records of the VCU Health System. Extracting data or otherwise recording any private health

information prior to IRB review is not permitted.

Keeping a Database of Prior Research Participants: For certain types of studies, this is a great resource! However, participants must first agree to have their name and contact information stored for this purpose. This agreement could be part of the consent process or a separate permission process. Both approaches require prior IRB review and approval in order to ensure the privacy of the individuals and confidentiality.

Eligibility Tracking: Particularly in clinical settings, participants may be evaluated (sometimes on a regular basis) to determine if they are eligible for research studies. However, if this process is a recruitment system, then it must be described within the IRB-approved protocol. Data collection for this "eligibility screening" approach must be IRB-approved and be coded so that identifiers can only be linked with the data by way of a code (that is also protected).



Privacy issues can crop up even before IRB approval is needed.

For more information about protecting personal and identifiable data, see the following resources:

- ["Privacy/Confidentiality Letter" November 16, 2007 \(Dr. Macrina\)](#)
- [VCU IRB WPP Guidance XVII-4: Research Involving Data Registries and Specimen Banks](#)
- ["Protecting Privacy and Maintaining Confidentiality of Data Collected for Research Purposes: IRB Perspectives \(11-23-07 Presentation\)"](#)
- *The Office of Education and Compliance Oversight* (for IRB-related questions) 827-2157 or mmarkow@vcu.edu
- *The Compliance Services Department—VCU HS* (for HIPAA-related questions) 828-0500 or cearnhar@vcu.edu or rcwillis@vcu.edu.

This "Bulletin" is a quarterly electronic publication of the Office of Education and Compliance Oversight (OEEO). 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.

Upcoming Events

- **January 25, 2008: The Research Incubator as a Resource for Research Coordinators** (*Research Coordinator 4th Friday Lunch & Learn Seminar Series*) 12:00 noon—1:00 pm; Children’s Pavilion—2017
- **February 1, 2008: Research in the Schools: Working with the IRB** 12:00 noon– 1:30 pm; Oliver Hall—Education—4084 Monroe Park Campus
- **February 22, 2008: Research Coordinator 4th Friday Lunch & Learn Seminar Series** 12:00 noon—1:00 pm; Children’s Pavilion—2017
- **February 26, 2008: “Clinical Research Billing Considerations: Challenges and Strategies”** Webinar Hosted by OECO; 12:00 noon—1:30 pm (check the [OECO calendar](#) for more information)
- **March 28, 2008: Research Coordinator 4th Friday Lunch & Learn Seminar Series;** 12:00 noon—1:00 pm; Children’s Pavilion—2017

Recent IRB Policy Changes:

<i>WPP</i>	<i>Title</i>	<i>Effective Date</i>
II-5	State Law Applicability for Research Conducted In and Outside of Virginia	10-15-07
XI-3	Legally Authorized Representative (Inclusion in Consent Process) - See also WPP#: XV-2 Assent / Informed Consent Considerations	10-15-07
XV-1	Permissible Categories (Children)	10-15-07
XV-3	Wards and Emancipated Minors	10-15-07

New Resource: Research Compliance Matrix

The VCU Office of Research has developed the [VCU Research Compliance Matrix](http://www.research.vcu.edu/p_and_g/research_compliance.htm), now available online at http://www.research.vcu.edu/p_and_g/research_compliance.htm. This navigational matrix was developed to facilitate the responsible conduct of research at VCU by serving as a single point of access for research policies and regulations, educational programs, forms, and submission procedures. Please feel free to provide feedback regarding this resource using the “feedback” button at the bottom of the page.

NEW REQUIREMENTS in Clinical Trial Protocol Registration !

Effective September 27, 2007, **US Public Law 110-85** expands the types of clinical trials which must be registered in [ClinicalTrials.gov](http://www.clinicaltrials.gov). This new law also expands the number of data elements which must be submitted to meet the registration criteria. **The deadline for complying with this law is December 26, 2007. Penalties for failure to register applicable clinical trials may include fines and the withholding or recovery of federal funding.**

All VCU investigators who currently have ongoing clinical trials (regardless of the funding entity) registered on ClinicalTrials.gov must **review and update their registration** by **December 20th** to ensure compliance with this deadline. For those investigators who have NIH funded clinical trials, please review the guidance at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>

Per the Clinical Trials Fact Sheet listed below, the types of Trials which must be registered include (1) Controlled clinical investigations of **drugs and biologics which are subject to FDA regulation** and (2) Controlled trials with health outcomes of **devices which are subject to FDA regulation**. Additional information regarding registration of applicable trials can be found at: <http://prsinformo.clinicaltrials.gov/s801-fact-sheet.pdf>.

For more information or questions, please contact Melanie Wiggins, Senior Contract and Grant Administrator, 827-4992 or mwig-gins@vcu.edu