



November 16, 2007

Vice President for Research

Francis L. Macrina, PhD

Dear VCU and VCUHS Investigators and Research Staff,

BioTech One, Suite 115
800 East Leigh Street
PO Box 980568
Richmond, VA 23298-0568

I am writing to remind you that you are responsible for protecting the personal and identifiable data of research subjects whether participants have been enrolled or are being tracked for eligibility. Data should never be transferred or stored in association with direct identifiers such as names, medical record numbers, social security numbers, or contact information. Data may be coded, however, the key to the code may not be stored with the data file. The following types of data issues apply to both biomedical and social-behavioral research: 1) feasibility determinations, 2) eligibility for participation in research, 3) transfer or receipt of datasets, and 4) storage of research data.

804-827-2262
FAX: 804-828-2051
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Feasibility determination

HIPAA regulations permit a review preparatory to research which allows a researcher to examine PHI (Personal Health Information) to determine the feasibility of performing a research protocol. All record review preparatory to research requires pre-approval from the Compliance Services Department, which manages HIPAA. The IRB acknowledges this preparatory activity and no IRB approval is needed for this preparatory review, provided the records review is only for feasibility and no identifiers are recorded with the data. During this period the researcher may not remove, or record and remove, any PHI from the VCU Health System.

Determining eligibility for recruitment

Eligibility tracking may involve close monitoring of potential subjects before recruitment begins. The process of obtaining such information should be described in the IRB protocol and must be approved. This type of data collection must be coded so that identifiers can only be linked with the data by way of a separately protected key.

Electronic transfer of datasets

Data electronically transferred to you, or by you, must be coded so that it is not associated with identifiers. The key to the code must be located separately from the data file. It is your responsibility to ensure that you do not send identifiable data and to remind others not to send identifiable data to you.

Storage of research data

Coding and password protecting files are the minimum-security requirements for protecting research information. When there are indirect identifiers such as date of service or date of birth or the sensitivity of the information being collected rises above minimal risk, additional protections, such as encryption, must be used

If you have questions concerning any of the above please contact the Office of Education and Compliance Oversight, 827-2157, e-mail msmarkow@vcu.edu OR the Compliances Services Department 828-0500, e-mail cearnhar@vcu.edu or rcwillis@vcu.edu.

Thank you for your continued attention to the protection of the human subjects who participate in research conducted at Virginia Commonwealth University.

Sincerely yours,

A handwritten signature in black ink that reads "Francis L. Macrina". The signature is written in a cursive style with a large, stylized initial 'F'.

Francis L. Macrina, Ph.D.
Edward Myers Professor of Dentistry and
Vice President for Research