




THE UNIVERSITY OF NORTH CAROLINA
AT CHAPEL HILL

Office of University Counsel

Campus Box #9105
The University of North Carolina
at Chapel Hill
Chapel Hill, NC 27599-9105

February 28, 2003

To: Covered Entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

From: B. Glenn George 
Privacy Officer and Interim University Counsel
University of North Carolina at Chapel Hill

Re: Disclosures of Protected Health Information to UNC-Chapel Hill Researchers

The purpose of this memorandum is to summarize procedures and compliance processes that UNC-Chapel Hill has developed to assure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We understand that you have a responsibility under HIPAA to limit access to Protected Health Information (PHI) and may be concerned about future or continuing access to that information by UNC-Chapel Hill researchers. At the same time, we know that you understand the importance of this research and the need for it to continue.

We believe that appropriate documentation, as described below, will permit the disclosure of PHI to UNC-Chapel Hill researchers, consistent with your obligations under HIPAA regulations.

As you may know, HIPAA **transition provisions** in 45 CFR 164.532 permit covered entities to disclose PHI to researchers without either an authorization or a waiver of authorization if the researchers have either (1) an informed consent document or other permission for the research study that was signed prior to April 14, 2003, by the individual; or (2) a waiver of informed consent for the research study that was granted by an Institutional Review Board (IRB) prior to April 14, 2003. UNC-Chapel Hill researchers who have either of these documents will be able to provide you with copies of them.

For research requests for fully identifiable protected health information that do not fall under the transition provisions described above, UNC-Chapel Hill researchers are able to present you with the following documentation of HIPAA compliance:

- (1) A copy of the authorization (meeting HIPAA standards) signed by the research participant; OR
- (2) A copy of the document stating the IRB's approval of a waiver of all or part of the authorization requirement; OR
- (3) A statement that the request for disclosure and research use of protected health information is limited solely to decedents; OR
- (4) A statement that the review of records is solely for the purpose of preparing a research protocol and PHI will not be removed from the facility.

For research requests for a limited data set, pursuant to 45 CFR 164.514(e), the University will execute a HIPAA-compliant data use agreement on behalf of our researchers. If you do not have a data use agreement form, we can provide one.

For research requests for completely de-identified data, pursuant to the standards of 45 CFR 164.514, no authorizations, waivers, data use agreements or other agreements are necessary for disclosure under HIPAA regulations. Such de-identified data do not constitute PHI under HIPAA.

We sincerely hope that this memo and the documentation described will provide you with adequate assurance of the HIPAA compliance of requests by UNC Chapel Hill researchers for disclosure of protected health information to their research studies. If you have additional questions about HIPAA compliance with respect to any request for disclosure of protected health information for use in a research study conducted by the University of North Carolina at Chapel Hill, please visit our website at <http://www.unc.edu/hipaa> or call the Office of University Counsel at (919) 962-1219.