October 18, 2004

TO:  Clinical Research Investigators and Coordinators

FROM: Dusty Layton
Office of Research Compliance and Assurance

RE: Revision of IRB Tissue Banking (Biological Materials) Policy

It is essential that investigators and IRB’s be aware of ethical issues raised by research involving human biological materials. Since our existing tissue banking policy caused some problems that were likely to increase the use of biological specimens and new research collections were developed, the IRB reviewed our current policies and has modified the policy, which is now referred to as storage of biological materials.

The current revision of the template for the storage of biological materials attempts to more clearly document an individual’s decision regarding the disposition of these samples. The instructions and template for banking biological materials are attached for your review. The IRB has changed it’s policy to require the exact use of the banking policy language within the consent form to now allow greater flexibility. However, this language must conform to specific criteria as outlined in Appendix H in the IRB Guidelines (Instructions for Storage of Biological Materials). In addition, other essential elements/sections have been added such as i) research results; ii) confidentiality and iii) right to withdraw.

All clinical research studies involving the use of biological materials should adhere to this new format effective immediately. If you have any questions, please call the Office of Research Compliance and Assurance. Thank you for your cooperation as we continue to improve our human subject’s protection program.