HIPAA Authorization
Instructions for Preparing Consent Documents For HIPAA Compliance

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule issued by the Department of Health and Human Services on December 30, 2000, establishes standards to protect the privacy of individually identifiable health information. The effective date for full compliance with the Privacy Rule is April 14, 2003.

The information in Attachment A explains specifically what the authorization to collect, use and share protected health information allows a researcher to do. Please carefully read the template language and craft it specifically for each research study.

These instructions apply to all research studies using individually identifiable health information that **will continue to recruit subjects on April 14th and after**. Subjects, who have signed consent documents prior to the 14th, do not need to re-sign a new form.

The consent template must be amended as follows:

1. Delete the section titled "What about Confidentiality?".
2. Insert the new section titled "What about Confidentiality of Records and Authorization to Use/Share Protected Health Information for Research" (see attachment A). This should be inserted as the last section in the consent (just prior to the signature section- see sample consent template in the IRB Manual Appendix C. http://www.newpaltz.edu/sponsored_programs . Follow the instructions in italics in attachment A to make the language study specific.
3. Add the section titled "Banking Specimens in Research," if applicable. (See Attachment B for language.) Make sure that this form only requests permission to bank the specimens, unless the future use can be specifically stated. The authorization for banking specimens cannot also serve as the authorization for future unknown uses of the specimens.
4. Delete the last section titled, "Consent"
5. Insert attachment C-for adult subjects, D-for adult & minor subjects, and E-for minor subjects.

Other Consent Considerations

1. The format of the document must be consistent throughout ["You (your child)", "You (your family member)"].
2. All *ITALICS* (i.e., instructions) must be removed.

Additional Requirements For Obtaining Consent/Authorization From Research Subjects

1. Subjects must be given a signed copy of the consent/authorization form.
2. Subjects must be given a copy of the (name of covered entity) at the time the consent/authorization form is signed.