I. Introduction:

The new HIPAA regulations require that extra care be taken to ensure that protected health information not be disclosed to third parties without the notification and proper authorization from the patients or research subjects. In this spirit, Informed Consent documents must be accompanied by HIPAA authorization for the disclosure of PHI and a notice of the Privacy Practice Policy of the Institution, department etc. sponsoring the study.

II.Guidelines:

Document must contain, as a minimum, the following information:

A. Authorization to disclose Protected Health Information:

1. A statement in which the patient or subject announces that s*h*e voluntarily authorizes the use and/or disclosure of the individual's protected and/or identifiable health information, in the circumstances or conditions to described.

2. The persons/organizations authorized to make the disclosures.

3. The individuals/organizations authorized to receive the information.
   a. Organization and department within the organization
   b. the individuals

4. The type or scope of the information that will be used or that is needed. (Ex. Demographic data, risk behavior data, medical history, specific laboratory results, etc.)

5. The purpose for the disclosure of the information

   a. Objective of the study
   b. Delicate or risky information that may be subtracted from the patients medical history (Ex. AIDS, STD, sexual habits, and others).

6. A statement that the individual may refuse to sign the authorization, and that said authorization may be revoked at any time in writing, to whom the subject must write the revocation and the corresponding address.

7. A statement that disclosure of the authorized information is voluntary, that refusal will not affect the patient's or subject's right to receive indicated medical treatment, and that the individual has the right to inspect the information that will be disclosed, as provided in CFR 164.524.

8. A statement that the subject understands that disclosure of information carriers the inherent risk for involuntary disclosure to unauthorized parties and that the information may not be protected by federal confidentially rules.

9. A statement about whom the patient may contact with questions about the disclosure of health information.

10. A statement that the authorization expires on the date the research study ends. There should be a blank for the date on the document.

11. A statement that the patient or subject will receive a copy of the authorization form.

12. A line for the subject's and witness' signature and the date of the signature.

B: Notice of Privacy Practices of the Institution and the department of the Institution sponsoring the study.

This document must contain the following:

1. A statement ensuring the commitment of the Institution, the department, the section to the protection of medical information. That the following describes how medical information will be used and communicated and how the subject may get access to this information.

2. Who will be committed to follow the rules established in the document. This must include a statement that the sponsoring agency, institution etc. may change this notice without previously notifying the subject. However, you will post the new notice in all research facilities and the subject may request a copy of the notice in each visit. The subject will sign each time s/he receives a copy of the Notice.

3. A statement that sharing of PHI can only occur with the subjects authorization.

4. Legal rights must be clearly described and must include the following information:

a. Right to see the person's own medical record. Right to see the specific medical information that will be shared for research purposes. The request must be in writing and sent to the principle investigator. A description of any information, if any, that will not be available for review by the subject, and in this case, to whom the research subject may refer to to protest.

b. Right to ask that any incorrect information be removed from the patients record.

c. Right to ask for a list of non-institutional or department parties with whom you have shared health information. This does not include information shared as authorized by the written permission.

d. Right to ask to limit how the individual's health information is used, and/or shared without the person's specific consent. The fact that you are not obligated to agree to the subject's request must be clearly stated. The request must be for a period under 6 years and must begin after April 14, 2003.

e. The subject has the right to requested confidential communications; contacts may be in certain ways or at certain location, means by which these communications can be done. These requests must be in writing, to the Doctor, or the clinic or medical office where the subject receives care, if this applies. Be as specific as possible within the scope and type of the study.

f. The subject has the right to receive a copy of this document.

g. Whom to contact if the subject believes his/ her rights have been violated.

h. Whom to contact for questions about this notice.

The following are references for other issues that may apply to individual studies The IRB encourages you to refer to these sites as you develop your own policies documents. Remember that you will need a version in Spanish as well as in English.

http://www.wvu.edu/rvrc/irb/hip_waiv.htm
http://www.wvu.edu/rvrc/irb/hip_auth.htp
http://library.ahima.org/xpedio/groups/public/documents/ahima/pub_bok1_016272.html
http://www.nefec.org/benefits/ROPHI.pdf
http://www.hipaadvisory.com/regs/finalprivacy/502.htm