Checklist for Incorporating Elements for a HIPAA Authorization into a Consent Form

It is recommended that you use this tool to ensure that each element of the required HIPAA Authorization is included. This language may be used in a hybrid consent/authorization form or for a "stand-alone" authorization.

	Required HIPAA Element	Example of Text (customize for your study)
	Who is requesting the PHI for research?	We are requesting your authorization to review your medical records
	Why is this information needed?	To determine whether you meet the conditions for participation in this study, to compare your earlier test results to the findings from this study, and if possible, to use your previous exam results in place of, or in addition to, some of the exams needed for this study.
	What will be disclosed?	We will obtain the following information: your diagnosis, age, past medical history, diagnostic procedures, and results of any tissue biopsies or blood tests, including results of genetic tests that were already done as part of your standard evaluation at the Cancer Center.
	Will research data be placed in the medical record? If yes, describe	As part of this research study, some information that we obtain from you will be placed into your medical records held at UPMC, including the results of pregnancy tests and other medical tests.
	How long will this information be made available to the researchers?	This identifiable medical record information will be made available to members of the research team for an indefinite period of time.
	Who (other than the investigators) will receive the PHI, and how will they use it?	Your medical information, as well as information obtained during this research study, may be shared with other groups for the purpose of monitoring this study, including authorized officials from the Food and Drug Administration, the National Cancer Institute, and the University Office of Research Protections. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide service and addressing billing and operational issues.
	Statement of the potential risk that PHI will be re-disclosed by a recipient:	We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.
	How long is the authorization valid?	This authorization is valid for an indefinite period of time.
	Right to revoke authorization; how to revoke:	However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing.
	Implications of revocation of authorization	If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.
	Implications of not signing form	*Note:* this need not be stated in the consent form but must be in the IRB protocol: Subjects who do not sign this consent form/HIPAA authorization cannot participate in the study
	Signature line should include last phrase	By signing this form, I consent to participate in this research study and provide my authorization to use and share my medical records