

 <b>JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH</b>	<b>Human Research Protection Program Policies &amp; Procedures</b>	
	Identification	Page 1 of 1
Title: <b>Informed Consent process</b>	Date Effective 9-16-04	Supercedes P&P dated

## Two Types of Written Consent

Consent must be documented by a *written* consent form that has been formally approved by CHR, unless CHR grants a waiver or alteration of this requirement. The written consent form may be either:

1. A *written document* that includes all of the basic elements of informed consent and additional elements, when appropriate; the document *must be signed by the subject or the LAR, or*
2. A *written short form* stating that all of the required elements of informed consent have been presented *orally* to the subject or the LAR. A *written summary or script* of what will be said to the subject is also required. The summary should include all of the elements of informed consent described above and be similar in content to a written consent. The short form *must be signed by the subject or LAR*, a witness who is not the person obtaining consent must sign both the short form and the summary, and the person obtaining the consent must sign the summary.

With either type of consent, copies of the written document or short form must be provided to the subject, and must also be retained on file by the principal investigator, with a copy of the written summary, if relevant, and put in the patient's medical records (when applicable).

Guidelines and suggestions for preparing a written consent or written summary that will be read to subjects are provided below. CHR has also developed a [Consent Form Template](#), a [Short Form Template](#) and a [Checklist for Consent Form](#) that include the elements of informed consent. All consent forms submitted for review by CHR should be verified with the checklist before submission to ensure they are complete.