

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

Federal Regulations

The Federal regulations require that legally effective consent be obtained from each research subject or legally authorized representative (LAR) and set out four overriding principles that are meant to apply to the consent process, unless there are specific exceptions made or allowed elsewhere in the regulations:

1. *Human research can proceed only with consent of the individual or the legally authorized representative.* Unless waived by CHR, no investigator may involve a human being as a subject in research without the legally effective consent of the subject or his/her legally authorized representative.
2. *Consent must be voluntary and given without undue influence.* An investigator must seek consent under conditions that provide the prospective subject and/or his or her legally authorized representative sufficient opportunity to consider whether to participate, and that minimize the possibility of coercion or undue influence.
3. *Consent must be in a language understandable to the subject or his/her legally authorized representative.*
4. *Waiver of rights is prohibited.* Consent, whether oral or written, may not include any exculpatory language through which the prospective subject and/or his or her representative is made to waive, or appear to waive, any of the subject's legal rights, or is made to release, or appear to release, the investigator, the sponsor, the institution or its agents from liability for negligence. See *Exculpatory Language* below.