

 <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

## Elements of Informed Consent

The Federal regulations require that certain information be provided to potential research subjects. These *required elements* of informed consent, and *additional elements* that should be included when appropriate, are shown below.

### Required elements:

1. Research purposes and procedures
2. Risks and discomforts
3. Anticipated benefits
4. Alternative procedures or treatments
5. Provisions for confidentiality
6. Compensation or treatment for injury
7. Whom to contact for information
8. Participation is voluntary

### Additional elements, when appropriate:

1. Unforeseeable risks
2. Termination of participation by the investigator
3. Additional costs to subjects
4. Consequences of leaving the study voluntarily
5. Notification of significant new findings
6. Approximate number of study subjects

Additionally, some studies may require elements not listed above. For example:

1. Consent to establish a tissue or specimen repository
2. Consent for possible commercial use of human tissues