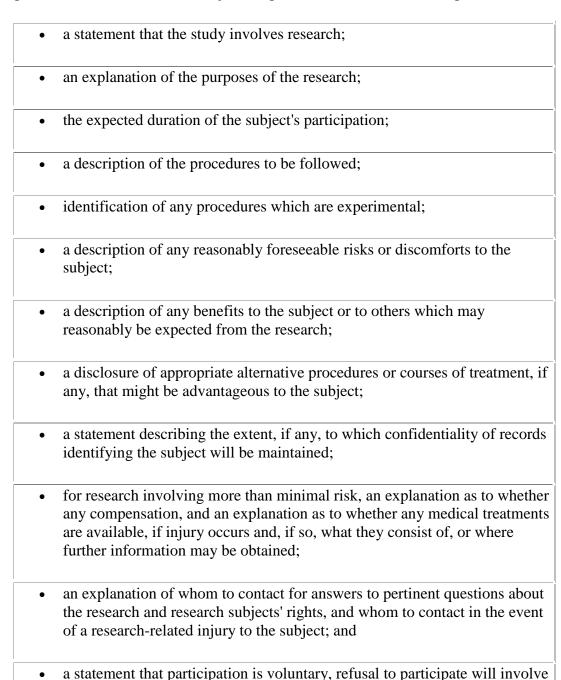
Required Elements of Informed Consent

The federal regulations (45 CFR 46.116) provide clear guidance on what information must be provided to human research subjects as part of the informed consent process:



no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or

loss of benefits, to which the subject is otherwise entitled.