

Elements of an Informed Consent Statement (ICS)

1. That the study involves research
2. The purpose of the research
3. The expected length of time of research participation
4. The procedures to be performed and which, if any, are experimental
5. Reasonably foreseeable risks and discomforts
6. Reasonably expected benefits to subjects or others
7. Alternatives, including treatment, that could benefit the individual more than research participation
8. The level of confidentiality protecting any identifiable information recorded on the subject
9. Whether compensation and medical treatment will be available for injuries resulting from research
10. The identity of the person(s) to notify if the subject has questions or suspects research-related injury
11. That participation is voluntary, refusal will not be penalized, and participation may cease at any time without penalty

