

# **ELEMENTS OF AN INFORMED CONSENT DOCUMENT**

## ***Excerpted From Required CITI Training***

*These elements are all required in full and expedited review applications. Only Basic Elements #1 and #2 (below) are required in exempt applications, though the other elements may be (optionally) included too.*

### Basic Elements

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A statement that participation is voluntary, refusal to participate will involve 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. For example, (students) may need to be assured that if they choose not to participate in a school-based study, their grades will not be affected.
3. A description of any reasonably foreseeable risks or discomforts to the subject.
4. A description of any benefits to the subject or to others, which may reasonably be expected from the research. If there are no direct benefits, the researchers may tell subjects what they hope to learn, how that knowledge will contribute to the field of study or how the knowledge might benefit others if such a case can be made.
5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. The description must include a full disclosure of any state-mandated reporting requirements, such as suspicion of child abuse and/or neglect or harm to others, when warranted by the topic under investigation.
6. For research involving more than minimal risk, an explanation as to whether any (resources) are available if injury occurs and, if so, what they consist of, what compensation will be provided, and where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

### Additional Elements

Depending upon the nature of the research and the risks involved, there may be additional required elements. For instance, incentives are payments or gifts offered to subjects as reimbursement for their participation. These must be described during the consent process as well as the conditions under which subjects will receive partial or no payment.

Subjects need to know, for example, how their compensation will be affected if they choose not to complete an interview. Discussion of what happens to data already collected if they withdraw midway through the study also may be addressed in this section.