Required Elements of Informed Consent

Federal regulations require that the following information must be conveyed to each participant in human subjects research.

- State that the study involves research:
  - Explanation of the purposes of the research and the
  - Expected duration of the subject's participation
  - Description of the procedures to be followed, and identification of any procedures which are experimental;
- Description of any reasonably foreseeable risks or discomforts to the subject;
- Description of any benefits to the subject or to others which may reasonably be expected from the research;
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- Description of the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- Explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- Detail 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; and
- 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.

Source: Informed Consent FAQs | HHS.gov

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