ELEMENTS OF INFORMED CONSENT*

1. A statement that the study involves research, an explanation of the purposes for the research and the expected duration of the subject's participation, a description of the procedures to be followed and the identification of any procedures which are experimental.

2. A description of any reasonable foreseeable risks or discomforts to the subjects.

3. A description of any benefits to the subject or to others which may be reasonably expected from the research.

4. A disclosure of appropriate alternate procedures or courses of treatment, if any, that might be advantageous to the subject.

5. A disclosure of appropriate alternate procedures or courses of treatment, if any, to which confidentiality of records identifying the subject will be maintained.

6. For research involving more than minimum risk, an explanation as to whether compensation for medical treatments is available if injury occurs and, if so, what they consist of, or where further information can be obtained.

7. An explanation of whom to contact for answers to pertinent questions about the research, and an explanation of the research subject's rights and whom to contact in the event of research related injury to the subject.

8. A statement that the 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.

9. Any additional costs to the subject that may result from the participation in the research.

10. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

11. The approximate number of subjects involved in the study.

*** OPRR Reports, March, 1983. pp. 9 & 10.**