

## **GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS**

### **INTRODUCTION**

The ethical principle of respect for persons requires that human research participants be given the opportunity to choose what shall and shall not happen to them. Valid informed consent requires: (1) disclosure of study procedures and potential risks to prospective research participants; (2) their comprehension of the information, and (3) their voluntary agreement, free of coercion and undue influence, to research participation.

All written informed consent documents must be complete and clearly written so as to promote informed decision-making by research participants in research activities.

### **REQUIREMENTS FOR INFORMED CONSENT**

Unless otherwise waived by the IRB, research investigators should obtain valid informed consent from all research participants (or their legally authorized representatives) who participate in their research studies. Generally, after the investigator has explained the research study to the research participant, the research participant's informed consent is documented by signing the protocol's written consent document, which the IRB must have previously reviewed and approved. The research participant is given a copy of the signed document. The original signed consent document is filed in a manner which ensures the research participant's confidentiality.

### **BASIC ELEMENTS FOR WRITTEN INFORMED CONSENT DOCUMENTS**

Unless otherwise authorized by the IRB, research investigators must provide the following information to each research participant in writing:

- a statement that the study involves research;
- an explanation of the purpose of the research and the expected duration of the research participant's participation;
- a description of the procedures to be followed and identification of any procedures that are experimental;
- a description of any foreseeable risks or discomforts to the research participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them;
- a description of any benefits to the research participants or to others that may reasonably be expected from the research;
- a disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the research participant;
- a statement describing to what extent records will be kept confidential, including a description of who may have access to research records;
- for research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if research participants are injured, where further information may be obtained, and whom to contact in the event of a research related injury;
- an explanation of whom to contact for answers to pertinent questions about the research and the research participant's rights; and
- a statement that participation is voluntary and that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which the research participant is otherwise entitled.