Elements of Informed Consent

Your informed consent document should address the following areas clearly.

A. Required Elements

Unless informed consent is waived or altered by the REC, the consent process must include the following basic elements:

• Statement that the study involves research, explanation of the purposes of the research, expected duration of participation, description of the procedures to be followed, and identification of any procedures that are experimental

• Description of any reasonably foreseeable risks or discomforts to the participant

• Description of any benefits to the participant or to others that may reasonably be expected from the research

• Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant (if the study is a trial)

• Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained

• Explanation of whom to contact for answers to pertinent questions about the research and research participant's rights and whom to contact in the event of a research-related injury to the participant (the should include contact information for BOTH the researcher and the Office of Research at Cave Hill)

• Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled

For research involving greater than minimal risk, an explanation about whether:

• Medical treatments are available if injury occurs and, if so, what they consist of or where further information can be obtained

• Compensation is available if injury occurs and, if so, an explanation as to what it consists of or where further information can be obtained.

• For research regulated by FDA, a statement that informs the participant of the possibility that FDA may inspect the records.

B. Additional Elements

One or more of the following elements will also be provided to potential participants during the consent process, when appropriate:

• Statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable

• Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent

• Any additional costs to the participant that may result from participation in the research

• Consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant

• Statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided

• Approximate number of participants involved in the study

Additional information beyond the basic and additional elements of consent (above) may also be required when the REC determines that this information would meaningfully add to the protection of research participants.

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