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GUIDANCE DOCUMENT: ADMINISTERING THE INFORMED CONSENT DOCUMENT

The purpose of this document is to provide guidance for Principal Investigators and their delegated research staff for administering the informed consent document to potential research participants. RCRC views informed consent as a process, not just a document. RCRC considers recruitment and advertising to be the start of the informed consent process. Additionally, consent should be viewed as a process over time and not an isolated event.

In accordance with 21 CFR 50.20 and 45 CFR 46.116, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirements, and should adhere to Good Clinical Practice and to the Ethical Principles that have their origin in the Declaration of Helsinki and The Belmont Report. The Principal Investigator or delegated research staff member must use only the RCRC current approved Informed Consent Document. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The following is suggested guidance to prompt a meaningful discussion with participants and their legally authorized representative. This guidance refers to:

Basic elements of informed consent

(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.

Points for discussion:

- Emphasize that the study involves research and describe what is being compared and why.
- Describe all study procedures, and tests.
- Describe which procedures are experimental and which are approved and/or standard of care.
- Describe all invasive procedures.
- Explain why each one is being done.
- Describe the probability for randomization (*i.e. you have a one in four chance...*).
- Explain how much of a time commitment is required.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

Points for discussion:

- Describe all known risk of the study drug or device in terms of how likely they are to occur.
- Describe unknown risks to an embryo, fetus, or nursing infant.
- Describe what assistance is available to relieve discomfort.
- Describe procedures that may cause discomfort.
- Include the risk of emotional discomfort.
- Explain any circumstances where the participant may feel uncomfortable such as in answering certain questions.

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

Points for discussion:

- Do not include payment for participation as a potential benefit.
- Describe any health benefits that are reasonably expected.
- Disclose that there may be no direct benefit to the participant.
- Indicate that information gained may help others in the future with the same disease, or condition.

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

Points for discussion:

- Specifically for treatment studies, describe alternative treatment options, their risks, and benefits.
- Describe how the potential participant may find out about alternative treatment options.
- If applicable describe the current “standard of care” for the particular disease or condition.
- If there are no alternate treatments, be sure that is understood.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration, Department of Health and Human Services (DHHS) or other supporting federal agencies may inspect the records.

Points for discussion:

- Describe how the data is collected and stored.
- Describe the circumstances under which research will be shared with others and how it will be protected.
- Describe the other people or entities that may have access to the participant’s research information and medical records (where applicable) such as the sponsor, IRB, FDA, DHHS, other supporting federal agencies and other monitors and auditors.
- Indicate that even if the results of the trial are published the participant’s identity will remain confidential.

(6) For research involving more than minimal risk, an 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.

Points for discussion:

- Describe the procedures for care if the participant suffers harm as a result of participation.
- Describe how the cost of care will be covered.
- Highlight any specific precautions the participant must take to minimize risk during their enrollment on study.

(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.

Points for discussion:

- Explain that the PI should be contacted for questions about the research study.
- Explain the process for reporting any adverse experiences, injury, or illness while on study.
- Explain the purpose of the IRB.
- Encourage participants to contact the IRB with questions, concerns, or complaints about the research.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Points for discussion:

- Stress to the prospective participant that the decision to enroll is entirely up to them.
- Ensure the prospective participant that there is nothing wrong with refusing to participate.
- Ensure the prospective participant that their relationship with the study doctor (if he/she is their own family doctor) will not be affected by their refusal to participate, and they will still receive regular care.
- Ensure the prospective participant that even if he/she decides to enroll now, he/she may always change their mind at any time during the study.

(9) A statement that a description of the clinical trial may be available on the web site, ClinicalTrials.gov as required by US Law, when applicable.

Additional elements of informed consent

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

Points for discussion:

- Indicate the investigational nature of the study, and clearly state that risks are unknown, and that is the reason for the research.
- Indicate whether or not a pregnancy test will be performed.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

Points for discussion:

- Participant refusal to adhere to protocol requirements and/or appointments.
- For treatment studies; if the participant is clearly not benefiting and/or regressing and there is an alternate treatment available.
- If the Sponsor, Investigator, or IRB terminates the study at any time for any reason.

(3) Any additional costs to the subject that may result from participation in the research.

Points for discussion:

- Describe any expenses that will not be covered such as transportation and parking.
- For device studies describe who will cover the cost of the device.
- For studies in which the participant will be billed for the test product, be sure that the participant is advised of the cost.
- Describe the anticipated payment for participation, and how payment will be prorated.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

Points for discussion:

- Discuss the importance of safely exiting the study.
- In treatment protocols, discuss other treatment options.
- If applicable discuss the danger of harm, including death if a participant voluntarily withdraws consent from treatment on study.
- If applicable discuss the risk of harm for abruptly discontinuing an investigational drug.

(5) 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.

Points for discussion:

- Advise the participant that they will be kept current with any developments during the course of the study that may affect their willingness to continue.
- Advise the participants about the process of evaluating results and the development of new drugs or treatments which their participation made possible.
- Be sure to state that the new information may not be all good or all bad.

(6) The approximate number of subjects involved in the study.

Points for discussion:

- Potential research participants may be interested to know if they are one of 5 or one of 500 that will participate in a particular research study.

(7) When seeking informed consent from participants, the following information regarding data retention and use must be included:

- **For FDA-regulated clinical trials:**
 - when a participant withdraws from a study, the data collected on the participant to the point of withdrawal will remain part of the study database and may not be removed
 - the consent document cannot give the participant the option of having data removed
 - **For research not subject to FDA regulations:**
 - the investigator should inform participants whether the investigator intends to either:
 - (1) retain and analyze already collected data relating to the participant up to the time of participant withdrawal;
- OR**
- (2) honor a research participant's request that the investigator destroy the participant's data or that the investigator exclude the participant's data from any analysis.

Additional Comments

- If the prospective participant elects to enroll be sure to verify that all additional questions are answered to their satisfaction and understanding.
- If the prospective participant elects to enroll be sure the Informed Consent Document is properly signed and dated by all parties.
- Allow prospective participants adequate time to make their decision.
- During the informed consent process it may be helpful for participants to take notes on the document or an additional piece of paper to help them remember or explain specific information. In some cases it may be necessary for participants to take the document home with them and discuss the study with a close friend or family physician.

SPECIAL PROVISIONS FOR CERTAIN POPULATIONS

RCRC will need to approve vulnerable populations prior to enrollment in the research. RCRC may require additional information or processes be used when consenting vulnerable populations. Once RCRC has granted approval for your research, please thoroughly read your approval letter or marked Informed Consent Documents for any requirements regarding these populations.