HRPP Document: **GUI304 — [II.7.C.]**
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Subject: **Statement on Elements and Disclosures for Informed Consent Process**

ORGANIZATIONAL STATEMENT

Unless waived by the IRB the following elements and disclosures, as applicable, will be disclosed to research participants.

Basic Elements of Informed Consent Process (required)

- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the participant's participation;
- A description of the procedures to be followed;
- Identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- 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 it consists of, or where further information may be obtained;
    - The UAB injury compensation clause must be included: "UAB has made no provisions for monetary compensation in the event of injury resulting from the research, and in the event of such injury, treatment is provided, but is not free of charge."
    - The sponsor's injury compensation clause must be included if the sponsor will pay for compensation to injured research participants, or pay for treatment of

research-related injuries (*Note: Investigator must provide verification of sponsor's injury compensation clause when sponsor will pay*.);

- If the sponsor will not provide any compensation for injuries related to the research, they include in the UAB injury compensation clause, "UAB and [name of sponsor] have made no provisions for monetary compensation…"

- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights and whom to contact in the event of a research-related injury to the participant (see FOR206 Sample Informed Consent Document);
- A 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;

Additional Elements, When Appropriate

When appropriate one or more of the following elements of information will be provided to each participant:

- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable (or to the embryo or fetus, if the participant is or may become pregnant). Examples of when the IRB requires this element are:
  - Phase I or II clinical investigations;
  - Experimental procedures or treatments with limited available data on risks.
- Any anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. Examples of when the IRB requires this element are:
  - If the sponsor may stop the study;
  - If the investigator reserves discretion to remove the participant from the study;
  - If the investigator may remove the participant from the study should the investigator determine it is in the best interest of the participant;
  - If the participant does not follow study instructions.

- Any additional costs to the participant that may result from participation in the research. Examples of when the IRB requires this element are:
  - If study procedures result in potential billing to the participant or third party payers;
  - If participants may have out-of-pocket costs from participation in the research (e.g., parking, meals, transportation);
  - If a possibility exists that a study drug become commercially available and no longer provided at no cost.
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant. Examples of when the IRB requires this element are:
  - If drug dose tapering is required and has risks to participants;
  - When a follow-up visit or testing is required for safety reasons.
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. The IRB generally requires this element unless good reasons are provided to exclude it.
- The approximate number of participants involved in the study. The IRB generally requires this element with respect to both the number of participants nationwide, if applicable, and locally.

Disclosures

In seeking informed consent, the following information will be disclosed to the participant unless waived by the IRB:

- Only IRB-approved advertisements and recruitment materials (See POL039 Policy on, PRO139 Procedure for Selection and Recruitment of Subjects in Research);
- If applicable, relevant animal data and their significance should be explained to potential participants;
- An explanation of measures to prevent pregnancy that should be taken while in the study, if applicable;
- A statement that notes the possibility that specific entities (e.g., UAB IRB, DHHS, FDA and foreign regulatory agencies, if appropriate) may inspect the research records;

- A statement that any reportable diseases/conditions detected during the research will be reported to the county or state health department:
    - Where HIV testing is conducted, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling before and after the testing;
    - Where other protocol testing for reportable diseases is conducted, individuals will be informed of the results and told where to obtain counseling and referred to their primary care physician or the state health department;
- Where drug screening is conducted, participants will be told that the results may exclude them from the study or if the information in the opinion of the investigator poses significant harm to the participant or risks to others that it will be reportable to a third party;
- Where DNA/genetic testing is conducted as part of the study, this information should be clearly stated and the testing will be limited to the disease under study or for other disease with the participants permission;
- When any other applicable federal, state, or local laws, require additional information to be disclosed to the proper authorities in cases such as:
    - child abuse and neglect;
    - elder abuse and neglect;
- When a participant is the first one to undergo a new procedure, this information should be clearly stated.
- For research involving biological or tissue specimens in conjunction with a clinical protocol:
    - A statement on retention and future use of biological or tissue specimens within the body of the study consent documents rather than a separate informed consent document including the following choices;
        - Limiting use for specified diseases;
        - Allowing unlimited use;
        - Contacting participants prior to use;
        - Option not to allow use of specimens for future research.

- A statement clearly noting that participants may refuse permission for future research use of their biological specimens without affecting their participation in the study or their care by the health provider;
- A statement that participants may change their mind and refuse to permit their specimens to be used at some time in the future to the extent their specimens are identifiable.