ROANOKE COLLEGE

Informed Consent Form
Format Guidelines

Introductory Paragraph:

Informed consent must begin with a concise and focused presentation of the **key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. FR46.116 (5)(i)

A brief description of these five factors will encompass the "key information" that is required in the introduction:

The Body of the Form includes the Basic Elements of Informed Consent:

Some of the elements listed below may repeat information that was provided in the Introduction. This section of the Informed Consent Form is designed to provide the potential participant with greater detail about each element or aspect of their consent.

- Study Information: A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental in nature.
- Foreseeable Risk or Discomforts: A description of any reasonably foreseeable risks or discomforts to the subject (for example, risks may be social, physical, emotional, or financial in nature). For research involving more than minimal risk, an explanation as to whether any compensation will be granted 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.
- Benefits: A description of any benefits to the subject or to others that may reasonably be expected from the research (***note***: compensation is not considered a benefit!).
- Confidentiality: A statement describing the extent to which confidentiality of records identifying the subject will be maintained.

- Contact Information: 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. This should be the primary investigator's contact information as well as the institutional IRB contact information.
- Voluntary Participation: A statement that 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.
- Future use of Data Collected: One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- Consent Statement and Signature Line: There must be designated space for the participant to print and sign their name and to date the document.
- **The person signing the Informed Consent Form must receive a copy of the form.**

Additional elements of informed consent that may or may not apply

- 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) that are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).