ROANOKE COLLEGE

Study Information Sheet
Format Guidelines

Introductory Paragraph:

Your Study Information Sheet 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 Study Information Sheet must be organized and presented in a way that facilitates comprehension.

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

The Body of the Sheet includes:

Some of the elements listed below may repeat information that was provided in the Introduction. This section of the Study Information Sheet 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.
- Health Information Portability and Accountability Act (HIPAA) Statement (if applicable): A section overviewing the Health Information Portability and Accountability Act (HIPAA), if private or health-related data will be collected.