***This is an example. You do not have to use the exact language here, but all relevant sections and information must be included. Be sure to change ID numbers and content to match your study!***

**Roanoke College**

**Study Information Sheet**

**Sample Template**

Key Information About this Study:

We would like to invite you to be in a research study about *(state the purpose of the study in clear, concise language for people who are not familiar with your research)*. Participation in this research is voluntary; you don’t have to take part if you don’t want to. If you decide to take part, you will *(****briefly*** *describe what the subject will do if they take part; study procedures, tasks they will complete, equipment they will use or which will be applied to them, where they will do this. You will provide more detail in the body of the form)*. Participation in this study will be for *(identify the amount of time the subject will be engaged in the research, including hours, days, weeks, months, number of sessions, duration of sessions and estimated time spent performing research activities [this may be the same as duration] and any follow-up time)*. Potential risks include *(provide potential risks, discomforts, and/or inconveniences that would be of most significance to subjects as a result of study procedures [for example, wearing study equipment, standing/sitting for extended time]. If there are no known risks then indicate “We believe there are no known risks connected to participating but there may be some we are not aware of”)*. The most likely potential benefits are *(there may be none for subjects; this can be stated as can potential future benefits to society if applicable)*.

Study Information

You are being asked to participate in a research study about…

***Note****: If the study involves deception or incomplete disclosure which necessitates a debriefing process, a general statement may be added here that more information will be given to subjects at the conclusion of the study, for example, "At the end of the study, we will explain in greater detail what we hope to learn from this research."*

What will I do if I choose to be in this study?

You will be asked to *(explain what the participant will be asked to do. Provide a clear, concise, complete description of what subjects will do or experience. Describe activities in chronological order to the extent possible. If there are many procedures, you may wish to use a table, list, or subheadings to organize the information better for the participant)*.

**Study time**: Study participation will take approximately *(state expected length of time--include the total time commitment, the number of visits/sessions involved, and the length of each visit/session)*.

**Study location**: All study procedures will take place at *(explain study location(s) -- if different procedures will take place at different locations, specify accordingly)*.

*(If you will be audio-recording or video-recording subjects, include the following)* I would like to audio-record *(or video-record)* this interview to make sure that I remember accurately all the information you provide. I will keep these files in *(explain where you will keep them)* and they will only be used by *(explain who will have access to the files)*. If you prefer not to be audio-recorded, I will take notes instead *(if audio/video recording are not optional, then clearly state that it is required for participation)*.

*(If you plan to quote statements made by participants, including the following)* I may quote your remarks in presentations or articles resulting from this work. A pseudonym will be used to protect your identity, unless you specifically request that you be identified by your true name.

What are the possible risks or discomforts?

*(explain any foreseeable risks to subjects here. Keep in mind that risks are not always immediate -- anger, emotional upset, or stress may appear later)*

Examples:

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

OR

Your participation in this study does not involve any physical or emotional risk to you beyond that of everyday life.

OR

Your participation in this study may involve the following risks *(describe any reasonably foreseeable risks to psyche, reputation, employability, insurability, social status, criminal or civil liability that may occur as a result of participation)*.

What are the possible benefits for me or others?

You are not likely to have any direct benefit from being in this research study. This study is designed to learn more about *(insert purpose/topic of study)*. The study results may be used to help other people in the future.

OR

Taking part in this research study may not benefit you personally, but we may learn new things that will help others.

OR

The possible benefits to you from this study include…

How will you protect the information you collect from me, and how will that information be shared?

Results of this study may be used in publications and presentations. Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used. *(if appropriate, add phrase such as "unless you give explicit permission for this below")*

To minimize the risks to confidentiality, we will *(explain data security measures to be taken, e.g., storage, coding, encryption, limited access to study records, etc. If disclosure of faces or voices is necessary to understanding the research and therefore identifying information may be used in reports/presentations, explain this and provide “I agree” “I do not agree” options at the end of the consent form)*.

What are my rights as a research participant?

Participation in this study is voluntary. You do not have to answer any question you do not want to answer. If at any time and for any reason, you would prefer not to participate in this study, please feel free not to. You may withdraw from this study at any time, and you will not be penalized in any way for deciding to stop participation. If you decide to withdraw from this study, the researchers will ask you if the information already collected from you can be used.

Will the data collected be used in future studies?

*(You must include one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens)*

1. *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*
2. *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.*

Health Information Portability and Accountability Act (HIPAA)

*(This section should**be removed if you* ***do not*** *intend to collect private/identifiable/health-related data from participants, but must be retained if you do intend to collect private/identifiable/health-related data from participants)*

There are rules to protect your private information. Federal and state laws, and the federal medical Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your ‘authorization,’ for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, medical history, audio and video recordings, and information from your medical records such, if applicable.

The research team may also need to disclose the information to others as part of the study's progress. Others may include the following: Sponsors, Contractors, Affiliates as appropriate, Roanoke College’s Institutional Review Board. While this study is being conducted you will not have access to your research-related health records.

This will not affect your healthcare, including your doctor’s ability to see your records as part of your normal care, and will not affect your right to have access to the research records after the study is completed.

To revoke your authorization, you must ask a member of the research team to give you a form to revoke the authorization. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a patient to treatment or benefit outside of the study.

If you revoke this authorization, *(faculty supervisor)* and their research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked before that time.

Your research records, and the information within them, will not be used for any purpose other than that described in this study as approved by the IRB.

Who can I contact if I have questions or concerns about this research study?

If you have questions, you are free to ask them now. If you have questions later, you may contact the researchers at *(add your contact information, including name, telephone number, and email address)*.

Or you can contact the office at Roanoke College:

Institutional Review Board

Roanoke College

221 College Lane

Salem, Virginia 24153

irb@roanoke.edu