The purpose of a **Study Information Sheet**, which can only be used in exempt research, is to enable potential research subjects to make an informed choice as to their participation in a study. The subject's participation is considered consent; the subject’s signature is not required.

The checklist and sample that follow are provided to assist you in the development of a Study Information Sheet. **Assistance in the preparation of the study information sheet is available. Contact the Office of Academic Grants, 375-2409, Trout 112.**

**Items 1-9 are required for a Study Information Sheet and each must be included in the study information sheet submitted if applicable to the proposed study.**

1. Use the heading “Roanoke College, Study Information Sheet”.
2. List the title of the project as given on your IRB form for this study.
3. Invite the subjects to participate and state that the study involves research and describe the following:
   a. purpose
   b. procedures (identify any that are experimental)
   c. expected duration of the subject's participation
   d. reasonably foreseeable risks or discomforts
   e. safeguards to be used to minimize risks
   f. any benefits to the subject or to others; or the extent of contribution to the body of literature/knowledge
4. Discuss briefly alternative procedures or courses of treatment, **if applicable**.
5. Describe the extent, **if any**, to which confidentiality of records identifying the subject will be maintained. (For example: Names will be recorded with the data but names will not be used in the report and will be destroyed at the end of the study. Data will be stored securely, only research personnel will have access to it. Your identifiable data will not be available to anyone outside this research project without your additional permission. **Or explain when and how confidentiality will be broken.**) If subjects are identified in reports, signed consent is required. If research is conducted over the internet, you must tell subjects that you cannot guarantee confidentiality while the data is on the internet.
6. State the terms of subject compensation for study participation, **if any**. If the subjects will be paid (or receive other compensation) for participation, state how and when they will receive payment and/or compensation. List value of gifts or service. If class credit will be given, list the amount and alternative ways to earn the same amount of credit. Explain the amount of partial payment if the subject withdraws prior to completion of the study.
7. Include an invitation for the subject to ask any questions at any time about the study and its procedures, or the subject’s rights. **Also, if applicable**, include a statement that if the subject experiences adverse effects, the investigator should be contacted immediately.
8. Include the investigator’s name, address, telephone number, and e-mail address that the subject may use to ask questions and report any study related problems. Include the Institutional Review Board, Roanoke College, Trout 112, Salem, Virginia 24153, 375-2409 as the place to contact with questions about participants’ rights.
9. Inform the subject that participation is voluntary. Further, state that 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. **The Federal regulations for the protection of human subjects require these words or an equivalent statement.** Tell subjects what will happen to their data if they withdraw from the study. **NOTE:** If no identifiers are recorded with the data, then once a subject’s participation is completed the data will not be identifiable to return or destroy.
If subjects are minors an Informed Consent Form must be used.

When appropriate, one or more of the following additional elements of information (items 10-19) also should be provided to each subject, in the Study Information Sheet:

10. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. (Explain what will happen to data if a subject withdraws. If data are gathered that contain subject identifiers, the disposition of the data must be stated.)

11. The approximate number of subjects involved in the study should be indicated when the subject population is small in number. If subjects might be identifiable in reports because individual responses will be described (possible when the N is small), a statement to this effect should be included in the consent statement or information sheet.

12. If you plan to audio tape, videotape or film the subjects, request permission to do so in writing and indicate how you will be using this material (research purposes only?, research and instruction?, who will have access to or view the tapes?, will subjects be allowed to preview the tapes?, what will happen to the tapes at the end of the study?; what will happen to the tapes if the subject withdraws?). All possible uses of the tapes/films/photos (current & future) must be described. If tapes are kept by the PI beyond the end of the study and/or archived, then the following statement must be included: “The tapes/films/photos will not be used for any additional purposes without your additional permission.” and signed/documented consent is required.

13. IF DECEPTION IS USED, include a statement to the effect that the research cannot be fully described at this time, but at the conclusion of participation, an explanation will be provided. (Provide a copy of the debriefing script with your packet for IRB review.)

14. Emergency Medical Treatment. If the study is Department of Health and Human Services (DHHS) funded, or if the study involves risk procedures (exercise, medical, stress, alcohol, and so on), the following paragraph is to be included:

"In the unlikely event of physical injury resulting from your participation in this research, emergency medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher if you are injured. If you require additional medical treatment you will be responsible for the cost. No other compensation will be provided if you are injured in this research."

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

17. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

18. Any additional costs to the subject that may result from participation in the research. (If subjects will be charged for participation in the research project, then all costs must be itemized on the consent form. If alternative, non-investigational procedures are available, then these procedures should be discussed and the average costs included in the consent form.)

19. A statement that significant new findings developed during the course of the research, and which may be related to the subject’s willingness to continue participation, will be provided to the subject.
You are invited to participate in a research study. (item 3) The purpose of this study is ...(item 3-a)

INFORMATION
Describe all procedures, preferably in chronological order, which will be employed in the study (item 3-b).
State the amount of time required of the subject per session and for the total duration of the study (item 3-c).

If applicable to your study, describe:
The number of subjects that will be participating in the research (item 12).
Information concerning taping or filming (item 13)

BENEFITS
Describe the benefits you anticipate will be achieved from this research, either to the subjects, others, or the body of knowledge. (item 3-f)

CONFIDENTIALITY (item 5)
Describe the extent, IF ANY, to which confidentiality of records identifying the subject will be maintained. OR explain when and how confidentiality will be broken.

COMPENSATION (item 6, if applicable add here)
For participating in this study you will receive _________________. Other ways to earn the same amount of credit are _________________. If you withdraw from the study prior to its completion, you will receive _________________.

CONTACT (items 7 & 8)
If you have questions at any time about the study or the procedures, you may contact the researcher, [name], at [address], [phone number], and [e-mail].
If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have not been honored during the course of this project, you may contact the office for the Institutional Review Board, Roanoke College, Trout 112, Salem, Virginia 24153, 540-375-2409, by e-mail at irb@roanoke.edu.

PARTICIPATION (items 9 & 11)
Your participation in this study is voluntary, you may refuse to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

Information Sheet date (date you construct or revise the form)
(Number pages, e.g., 1 of 1)

(Indicate on a separate page whether this information will be presented orally or given to the subjects in written form. If provided in written form, duplicate copies are not necessary, as no signature is required.) In nearly all cases the IRB will require that the information be provided in written form. Check with the office for cases where oral presentation is acceptable.)