An Informed Consent Statement has two purposes: (1) to enable potential research subjects to make an informed choice as to their participation in a study, and (2) to document their decision to participate. In order to make an informed choice, potential subjects must understand the study, how they are involved in the study, what sort of risks it poses to them, and what to do if something untoward happens. The words and language used to describe these factors must be understandable to potential subjects.

The checklist and sample that follow are provided to assist you in the development of an Informed Consent Statement. Assistance in the preparation of the consent statement is available. Contact the Office of Academic Grants, 375-2409, Trout 112.

Items 1-10 are required elements of an Informed Consent Statement and each must be included in the informed consent statement submitted.

1. Use the heading "Roanoke College, Informed Consent Statement".

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, Administration 209, 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.

10. Include a statement that says the subject has read the consent form, has had questions answered to his or her satisfaction, acknowledges receiving a copy of the form, and agrees to take part in the study. Provide a line for signature(s) and the date. Provide two copies of the Consent Form, one to be retained by the subject and one to be signed by the subject and, if applicable, the subject’s parent(s)/guardian/legal representative and returned to you.
If subjects are minors use the following guidelines for obtaining consent/assent:

a. **6 years old and younger** - only parent(s)/guardian/legal representative need sign;

b. **7-8 years old** - signature of minor is optional, requires signature of parent(s)/guardian/legal representative;

c. **9 through 17 years old** - requires signature of both minor and parent(s)/guardian/legal representative.

When younger children are subjects, a script that will be used to explain the study to the children must be submitted for review.

If the subject or legal representative is unable to read and understand the written consent form, it must be verbally presented in an understandable manner and witnessed (with signature of witness). This might apply in cases where subjects are: MENTALLY DISABLED, SERIOUSLY ILL, INSTITUTIONALIZED, INCARCERATED (PRISONERS), or OTHER VULNERABLE GROUPS.

When appropriate, one or more of the following additional elements of information (items 11-19) shall also be provided to each subject, in either the Informed Consent Statement:

11. 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.)

12. 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.

13. 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/document consent is required.

14. **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.)

15. **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.
ROANOKE COLLEGE
INFORMED CONSENT STATEMENT (item 1)
[List title of project here] (item 2)

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. Point out any that are considered experimental and explain technical and medical terminology (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:

Alternative procedures or courses of treatment [when experimental procedures are being used] (item 4).

The number of subjects that will be participating in the research (item 12).

Information concerning taping or filming (item 13).

A disclaimer for the use of deception (item 14).

RISKS

List the foreseeable risks or discomforts, if any, of each of the procedures to be used in the study, and any measures which will be used to minimize the risks (items 3-d & e).

EMERGENCY MEDICAL TREATMENT (item 15, if applicable add here)

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.

BENEFITS

List the benefits you anticipate will be achieved from this research, either to the subjects, others, or the body of knowledge (item 3-f). (There may be no direct benefits to the subjects, but benefits to the body of knowledge in general.)

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 .

(Number pages, e.g. 1 of 2) __________

CONTACT (items 7 & 8)

_________________________  subject’s initials
If you have questions at any time about the study or the procedures, or you experience adverse effects as a result of participating in this study, 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 been violated 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 any time 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.

**CONSENT** (item 10)

I have read this form and received a copy of it. I have had all my questions answered to my satisfaction. I agree to take part in this study.

Subject's signature__________________________________________ Date _________________

I agree to allow my child, ________________________, to take part in this study.

Parent's signature__________________________________________ Date _________________

Witness signature__________________________________________ Date _________________

(required if form is read to subject)

Consent form date: (date you construct or revise the form)

(Number pages, e.g., 2 of 2)

**NOTE TO INVESTIGATORS:**

1. Researchers are urged by the IRB to use the wording in the checklist and sample, as it applies to their study, and to follow the format of the sample, unless researcher supported reasons are provided for the alternatives. The form should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.

2. Study Information Sheets for mail surveys may take the format of a letter, as long as all required information is included.

3. For studies done in a foreign country or with subjects speaking a foreign language, indicate if the Informed Consent Statement or Study Information Sheet is to be in a foreign language, submit the foreign language version and an English translation.

4. Be sure to follow the directions in item 10 on the checklist for preparing the signature lines. Separate forms should be prepared when young minors are used; one for the minors and one for the parents. If the minors are age 15 and above a single form may be acceptable with signature lines for both the minor and parent. A script of what will be said to young children should be submitted.

5. Be sure to include any of items 11-19 on the checklist that are appropriate to your study. While items 16-19 are not specifically covered in the sample, if they apply to your study they must be included.