**ROANOKE COLLEGE**

**HUMAN SUBJECT RESEARCH**

**FULL APPLICATION**

The Roanoke College Institutional Review Board (IRB) must review and approve all research involving human subjects before data collection begins.Each of the items in the form that follows must be completed and the form signed before it is submitted. If the form is being submitted by a student, the faculty member who is supervising the student also must sign the form. The form with all required signatures and attachments **must be forwarded electronically** to the Institutional Review Board (with signatures and attachments) to irb@roanoke.edu.

**CHECKLIST OF ITEMS THAT MUST BE SUBMITTED:**

[ ]  Completed and signed Review Form

[ ]  Copy of interview or focus group questions, written questionnaires, or instruments that will be used in the study.

[ ]  Informed Consent Form

[ ]  Documentation of competence in the rules and procedures governing ethical treatment and use of human research participants. This may be done by providing evidence of previous training. There are two online courses available for this purpose—**choose one**.

* 1. CITI online course <http://www.citiprogram.org>. (Human Subjects Research-Social & Behavioral Research)
	2. NIH online course <http://phrp.nihtraining.com/users/login.php>.

[ ]  If deception is used in the study, a statement that will be used in debriefing the subjects must be included.

**COMPLETE THE IRB FORM, PRINT IT, AND ADD THE APPROPRIATE SIGNATURES.**

 **FORWARD THE SIGNED FORM AND REQUIRED ATTACHMENTS**

**ELECRONICALLY TO** **irb@roanoke.edu**

**HAND WRITTEN FORMS WILL BE RETURNED WITHOUT REVIEW.**

**ROANOKE COLLEGE**

**HUMAN SUBJECT RESEARCH**

**FULL APPLICATION**

Project Title:

Projected Data Collection Start Date: End Date:

Principal Investigator Department

Address E-mail

Project Category:

 [ ]  Faculty/Staff Research Project. Funding Agency

 [ ]  Student Research Project. Course # Professor

 [ ]  Class Research Project (Faculty Only). Course Number

 [ ]  Other Type of Research Project. Describe project type

 [ ]  IRB Renewal of Previously Approved Project. IRB Study #

 [ ]  Modification to Previously Approved Project (attach changes). IRB Study #

PRINCIPAL INVESTIGATOR: As the principal investigator, I pledge to conform to the following:

1. As one engaged in investigation utilizing human subjects, I acknowledge the rights and welfare of the human subject involved.
2. I acknowledge my responsibility as an investigator to secure the informed consent of the subject by explaining the procedures, in so far as possible, and by describing the risks as weighed against the potential benefits of the investigation.
3. I assure the IRB that all procedures performed under the project will be conducted in accordance with those Federal regulations and Roanoke College policies that govern research involving human subjects.
4. Any deviation from the project (e.g., change in principal investigator, research methodology, subject recruitment procedures, etc.) will be submitted to the IRB in the form of an amendment for its approval prior to implementation.

PI Name Signature Date

FACULTY SPONSOR*:* As the faculty sponsor, my signature testifies that I have reviewed this application and that I will oversee the research in its entirety, through the termination report.

Faculty Name Signature Date

**IRB REVIEW – FOR IRB USE ONLY**

This protocol for the use of human subjects has been reviewed by the Roanoke College Institutional Review Board, and the following action has been taken:

 □ Administrative Approval □ Expedited Approval □ Full Approval □ Not Approved

Study Number: Approved Dates: to

IRB Chairperson/Director Signature: Date:

**ROANOKE COLLEGE**

**HUMAN SUBJECTS RESEARCH**

**REVIEW CHECKLIST**

**Please indicate whether any of the following conditions apply to this research project. Place a check in the appropriate box(es).**

[ ]  Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

[ ]  Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination

[ ]  Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination

\*For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

\*If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

[ ]  Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

[ ]  Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

[ ]  Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

[ ]  Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations

[ ]  Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §\_\_.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §\_\_.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §\_\_.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

**ROANOKE COLLEGE**

**HUMAN SUBJECT RESEARCH**

**IRB REVIEW FORM**

1. **PURPOSE:** Briefly describe, in lay terms, the general nature and purpose of the proposed research, and where the study will take place.
2. **BENEFIT TO SCIENCE/SOCIETY/ROANOKE COLLEGE:** Describe information that may accrue to science, society, and/or the Roanoke College community in general as a result of this work:
3. **PROCEDURES:** List all procedures to be used on human subjects or describe what subjects will do.
	1. If done during regular class time, explain what non-participants will do.
4. Please complete the following section **if you are administering a survey to a Roanoke College group** (faculty, staff, students, etc.):
	* 1. How will the survey be administered? (e.g. paper survey, or Qualtrics)
		2. Which Roanoke College group will you be administering the survey to(check all that apply):

[ ]  Students [ ]  Alumni [ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Faculty ☐ Staff

Do you need a specific subset of the population referenced above (example: Female student athletes, International students, etc.)? If so, what subset are you requesting?

* + 1. What institutional information, if any, do you need in order to administer your survey? (e.g., names, e-mail, address information, etc.) Only data allowed by FERPA can be used.

NOTE: If you are sending the survey to a Roanoke College group, researchers will need to contact the Institutional Research office once IRB approval is complete ([ir@roanoke.edu](ir%40roanoke.edu)) to have that office send an invitation on their behalf,.

Survey invitations are sent to a matched subset of the student body, not the entire student population.

One reminder invitation can be sent about a week after the initial invitation, if needed. The researcher will need to contact the Institutional Research office to request that reminder. Reminders are sent to the same mailing list as was used the first time.

* + 1. Subject line of the proposed invitation:
		2. Body text of the proposed invitation:
		3. Survey URL:
1. **SUBJECT RECRUITMENT:**
	1. Describe the group from which your subjects will be selected (e.g., Roanoke College students, faculty, staff, or alumni; general public, high school students, etc.).
	2. Describe the process by which subjects will be recruited:
	3. Number of subjects that you hope to involve in the research:
	4. Amount of time that will be required of subjects:
	5. Specific eligibility requirements for subjects (or describe screening procedures), including those criteria that would exclude otherwise acceptable subjects.
	6. If your study uses only male or female subjects, explain why.
	7. Relationship between researcher and subjects - such as, teacher/student; employer/employee; or superintendent/principal/teacher:

1. **VULNERABLE SUBJECTS:** Check appropriate box for type of vulnerable subject population involved when investigation specifically studies:

[ ]  minors (under age 18), [ ]  pregnant women, [ ]  persons with mental disabilities,

[ ]  prisoners, [ ]  economically or educationally disadvantaged,

[ ]  persons with physical disabilities, [ ]  other vulnerable population.

If any of the above are used, state the necessity for doing so. Also, indicate the approximate age range of minors to be involved.

1. **RISKS TO SUBJECTS:**
	1. State the potential risks - for example, physical, psychological, financial, social, legal or other - connected with the proposed procedures.
	2. Briefly describe how risks to subjects are reasonable in relation to anticipated benefits.
	3. Describe procedures for protecting against, or minimizing, potential risks. Assess their likely effectiveness.
	4. If you are using an electrical device that is attached directly to subjects explain how the subjects will be protected from shock.
2. **RESULTS:** How will results be used (e.g. only in a class, only on our campus, off campus conferences, displayed publicly)? Include current uses and any possible future uses.
3. **CONFIDENTIALITY**
	1. Describe methods for preserving confidentiality.
	2. How will data be recorded and stored, with or without identifiers? If identifiers are used describe the type: names, job titles, number code, etc. How long are identifiers kept? If coding system is used, is there a link back to the subject’s ID? If yes, where is the code list stored in relation to data and when is the code list destroyed?
	3. Will reports be written in aggregate terms, or will individual responses be described?
	4. Will subjects be identified in reports? If so, why?
	5. If audio or visual recording is used, describe disposition of recordings at the end of the study. If tapes are to be kept, indicate for how long and describe future uses of tapes.
4. **BENEFITS TO SUBJECTS:**
	1. What, if any, benefit is to be gained by the subject?
	2. In the event of monetary gain, include all payment arrangements (amount of payment and the proposed method of disbursement), including reimbursement of expenses.
	3. If class credit will be given, list the amount and the value as it relates to the total points needed for a grade. List alternative ways to earn the same amount of credit. Explain the amount of partial payment/class credit if the subject withdraws prior to completion of the study.
	4. If merchandise or a service is given, indicate the value

I. **CO-INVESTIGATORS, COOPERATING DEPARTMENTS, COOPERATING INSTITUTIONS:** If there are multiple investigators, please indicate only one person on the Human Subject Research Form as the principal investigator; others should be designated as co-investigators here. **Co-investigators should sign here, pledging to conform to the sentences on the Application Form.** If you anticipate that another department or institution may be involved in this research, list that here. If you are working with another institution, please include a letter of cooperation from that institution. **Please provide the person’s name and e-mail address.**

Co-investigator 

 E-mail 

 Signature

Co-investigator 

 E-mail 

 Signature

Co-investigator 

 E-mail 

 Signature

Co-investigator 

 E-mail 

 Signature

Co-investigator 

 E-mail 

 Signature

**IMPORTANT!!** The IRB Review Form must be signed by all parties and include the following items:

1. Copy of interview or focus group questions, written questionnaires, or instruments that will be used.
2. Informed Consent Form
3. Documentation of competence in the rules and procedures governing the ethical treatment and use of human research participants. This may be done by providing evidence of previous training. There are to online courses available for this purpose—**choose one**.
	1. CITI online course <http://www.citiprogram.org>.
	2. NIH online course <http://phrp.nihtraining.com/users/login.php>.
4. If deception is used, include the subject debriefing statement that will be used.