

IRB Exempt Registration Form Social/Behavioral/Education Research

This is a 3 Step process:

1. Enter Basic Project Information
2. Determine Exemption Category
3. Email a signed copy of the Form to irb@roanoke.edu

You may not begin your research project until all three steps are complete.

If at any point while completing this form you are unsure how to answer a question, feel free to reach out to the IRB Chair, Dr. Alice Kassens (540-375-2428 or kassens@roanoke.edu), or to the IRB Administrative Support, Mrs. Susan Rambo (375-2204 or srambo@roanoke.edu). If you discover during the process of completing this form that your project is not eligible for one of the Exemption Categories, you cannot use the Exempt Registration Form. Instead, you must complete an Expedited/Full Application Form.

[Expedited/Full Application Form](#)

Step 1: Basic Project Information

Information:

Principal Investigator

Email

Faculty Supervisor

Course

Title of your Project

Create a unique **IRB Project ID** by using the current academic year, the Principal Investigator's last name, and the first word of the project title (other than a, an, or the).

For Example: Dr. Doe completes the form during the 2019-20 academic year for a project titled "An Analysis of Sorts." The IRB Project ID would be "201920_Doe_Analysis"

- **Include your IRB Project ID in the subject line of all email communication with IRB related to your project**

Does your project meet the IRB definition of “research?”

- ☐ No – **STOP, you do not need to complete an Exempt Registration Form or an Application for IRB Administrative Review. Your project does not fall under IRB oversight.**
- ☐ Yes – **Continue to the next item**

Does your project meet the IRB definition of “human subject research?”

- ☐ No – **STOP, you do not need to complete an Exempt Registration Form or an Application for IRB Administrative Review. Your project does not fall under IRB oversight.**
- ☐ Yes – **Continue to the next item**

Is this research being funded by an external organization?

- ☐ No – **Continue to the next item**
- ☐ Yes – **STOP, the research DOES NOT qualify for an Exempt Registration process.**

-Have you AND you co-investigators (if any) completed and submitted your Human Research Subject training?

- ☐ No – **STOP, you must submit your training certificate to be eligible to use the Exempt Registration Form.**
- ☐ Yes – **Continue to the next item**

-Are members of any protected population going to be potential research participants (check all that apply):

- ☐ Minors (under age 18)
- ☐ Prisoners
- ☐ Persons experiencing diminished capacity
- ☐ Mentally or physically challenged individuals
- ☐ Pregnant individuals
- ☐ None

If you encountered any “STOP” prompts in your question responses, you may not use the Exempt Registration Form to register your research project. You must submit an Application for IRB Administrative Review.

The next step in the process is to identify which Exempt Category your project fits under if any at all. Some projects fit into more than one Exempt Category; however, you only need to meet the criteria of one category in order to use this form.

Summary of Exempt Categories:

- **Category #1 – Educational Exemption**
- **Category #2 – Survey, Interview or Observation of Public Behavior**
- **Category #3 – Benign Behavioral Intervention**
- **Category #4 – Secondary Use of Data**
- **Category #5 – Federally Supported Research**
- **Category #6 – Taste and Food Quality**

Select the applicable exemption category(ies) and answer the appropriate questions that follow:

☐ **Category #1 – Educational Exemption**

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.

If Category #1 is selected, answer the following questions:

Will the research occur in a commonly accepted educational settings?	<input type="checkbox"/> No – STOP, the research DOES NOT qualify for Exemption under Category #1 <input type="checkbox"/> Yes
Will any research methods deviate from normal educational practices?	<input type="checkbox"/> No <input type="checkbox"/> Yes – STOP, the research DOES NOT qualify for Exemption under Category #1
Could any aspects of the research have adverse impacts on the students or the teachers?	<input type="checkbox"/> No <input type="checkbox"/> Yes – STOP, the research DOES NOT qualify for Exemption under Category #1
If your research: <ol style="list-style-type: none"> 1. meets the criteria of Exempt Category #1 as described above AND 2. you did not encounter a “STOP” prompt while answering the Category #1 questions then your research can be classified as Exempt under Category #1. Please complete the “Signature Page” at the end of the form and submit a signed copy to irb@roanoke.edu	

Category #2 – Survey, Interview or Observation of Public Behavior 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 Category #2 is selected, answer the following questions:	
Is information recorded in a manner where participants can be identified (directly, i.e. name is collected; or through identifiers linked to the subjects, i.e. phone number, ID, etc).	<input type="checkbox"/> No – If your research meets the criteria of Exempt Category #2 as described above and you answered “No,” you can stop here. The project can be classified as Exempt under Category #2. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu <input type="checkbox"/> Yes – Continue to the next questions
Would disclosure of responses outside of the research team place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement or reputation?	<input type="checkbox"/> No – If your research meets the criteria of Exempt Category #2 as described above and you answered “No,” the project can be classified as Exempt under Category #2. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu <input type="checkbox"/> Yes – STOP, the research DOES NOT qualify for Exemption under Category #2
If your research: <ol style="list-style-type: none"> 1. meets the criteria of Exempt Category #2 as described above AND 2. you did not encounter a “STOP” prompt while answering the Category #2 questions then your research can be classified as Exempt under Category #2. Please complete the “Signature Page” at the end of the form and submit a signed copy to irb@roanoke.edu	

<input type="checkbox"/> Category #3 – Benign Behavioral Intervention 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	
If Category #3 is selected, answer the following questions:	
Is information recorded in a manner where participants can be identified (directly, i.e. name is collected; or through identifiers linked to the subjects, i.e. phone number, ID, etc).	<input type="checkbox"/> No – If your research meets the criteria of Exempt Category #3 as described above and you answered “No,” you can stop here. The project can be classified as Exempt under Category #3. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu <input type="checkbox"/> Yes – Continue to the next questions
Would disclosure of responses outside of the research team place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement or reputation?	<input type="checkbox"/> No – If your research meets the criteria of Exempt Category #3 as described above and you answered “No,” the project can be classified as Exempt under Category #3. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu <input type="checkbox"/> Yes – STOP, the research DOES NOT qualify for Exemption under Category #3
If your research: 3. meets the criteria of Exempt Category #3 as described above AND 4. you did not encounter a “STOP” prompt while answering the Category #3 questions then your research can be classified as Exempt under Category #3. Please complete the “Signature Page” at the end of the form and submit a signed copy to irb@roanoke.edu	
<input type="checkbox"/>	

<input type="checkbox"/> Category #4 – Secondary Use Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.	
If Category #4 is selected, answer the following questions:	
Will any investigators have contact with any subject(s) in the data set?	<input type="checkbox"/> No – Continue to the next questions <input type="checkbox"/> Yes – STOP, the research DOES NOT qualify for Exempt category #4
Can the information or biospecimen in the data set be linked back to an individual?	<input type="checkbox"/> No – STOP, the research is not regulated and DOES NOT fall under the Roanoke College IRB <input type="checkbox"/> Yes – Continue to the next questions
Is the information or biospecimen data set publicly available?	<input type="checkbox"/> No – Continue to the next questions <input type="checkbox"/> Yes – You can stop here. The project can be classified as Exempt under Category #4. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu
Will researchers record information in a manner where participants can be identified (i.e.	<input type="checkbox"/> No – You can stop here. The project can be classified as Exempt under Category #4.

identifiable information is kept, master list kept after data collection, key personnel can re-identify individuals, etc.)?	Please note this at the end of the form and submit a signed copy to irb@roanoke.edu <input type="checkbox"/> Yes – Continue to the next questions
Does the research only involve 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);	<input type="checkbox"/> No – Continue to the next questions <input type="checkbox"/> Yes – You can stop here. The project can be classified as Exempt under Category #4. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu
Will the research be conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities?	<input type="checkbox"/> No – STOP, the research DOES NOT qualify for Exempt category #4 <input type="checkbox"/> Yes – You can stop here. The project can be classified as Exempt under Category #4. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu
If your research: <ol style="list-style-type: none"> 1. meets the criteria of Exempt Category #4 as described above AND 2. you did not encounter a "STOP" prompt while answering the Category #4 questions then your research can be classified as Exempt under Category #4. Please complete the "Signature Page" at the end of the form and submit a signed copy to irb@roanoke.edu	

Category #5 – Federally Supported Research

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. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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.

If Category #5 is selected, answer the following question:

Does your project meet the category 5 description of Federally Supported Research?	<input type="checkbox"/> No – STOP, the research DOES NOT qualify for Exempt category #5 <input type="checkbox"/> Yes – You can stop here. The project can be classified as Exempt under Category #5.
--	---

	Please note this at the end of the form and submit a signed copy to irb@roanoke.edu
If your research: <ol style="list-style-type: none"> 1. meets the criteria of Exempt Category #5 as described above AND 2. you did not encounter a “STOP” prompt while answering the Category #5 questions then your research can be classified as Exempt under Category #5. Please complete the “Signature Page” at the end of the form and submit a signed copy to irb@roanoke.edu	

<input type="checkbox"/> Category #6 – Taste and Food Quality Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or 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	
If Category #6 is selected, answer the following question:	
Does your project meet the category 6 description of Taste and Food Quality studies?	<input type="checkbox"/> No – STOP, the research DOES NOT qualify for Exempt category #6 <input type="checkbox"/> Yes – You can stop here. The project can be classified as Exempt under Category #6. Please note this at the end of the form and submit a signed copy to irb@roanoke.edu
If your research: <ol style="list-style-type: none"> 1. meets the criteria of Exempt Category #6 as described above AND 2. you did not encounter a “STOP” prompt while answering the Category #6 questions then your research can be classified as Exempt under Category #6. Please complete the “Signature Page” at the end of the form and submit a signed copy to irb@roanoke.edu	

Signature Page
IRB Exempt Registration

Principal Investigator: _____

Email: _____

Faculty Supervisor: _____

Course: _____

Title of your project: _____

Project Eligibility for Exemption: I have worked through the checklist and verified that my project is eligible for Exemption under the following Category(ies):

- ☐ **Exempt Category 1—Educational Exemption**
- ☐ **Exempt Category 2—Survey, Interview or Observation of Public Behavior**
- ☐ **Exempt Category 3—Benign Behavioral Intervention**
- ☐ **Exempt Category 4—Secondary Use**
- ☐ **Exempt Category 5—Federally Supported Research**
- ☐ **Exempt Category 6—Taste and Food Quality**

PRINCIPAL INVESTIGATOR, CO-INVESTIGATORS, COOPERATING DEPARTMENTS, COOPERATING INSTITUTIONS: If there are multiple investigators, please indicate only one person as the principal investigator; others should be designated as co-investigators here. The **Principal Investigator and Co-investigators should sign here, pledging to conform to the statements made on this form.**

Have you completed and submitted you Human Research Subject Training?

☐ Yes ☐ No

Principal Investigator: _____

Signature: _____

Co-Investigator: _____

Signature: _____

Co-Investigator: _____

Signature: _____

Survey Information

-Do you intend to survey a Roanoke College group electronically (faculty, staff, student, etc.)?

- ☐ No
- ☐ Yes

-What groups to you intend to survey? Check all that apply:

- ☐ Roanoke College Student
- ☐ Roanoke College Faculty
- ☐ Roanoke College Staff

If yes, please provide the following:

- i. Subject line of the proposed invitation:
- ii. Body text of the proposed invitation:
- iii. Survey URL:

Glossary of Terms

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy. For purposes of this part, the following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.*, a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Risk: The probability of harm (physical, psychological, social, legal, or economic) occurring as a result of participation in a research study. Both the probability and the magnitude of possible harm may vary from minimal to significant.

-Physical risks: include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. A physical risk may result from the involvement of physical stimuli such as noise, electric shock, heat, cold, electric magnetic or gravitational fields, etc. Engaging a subject in a social situation which could involve violence may also create a physical risk.

-Psychological risks: include the production of negative affective states such as anxiety, depression, guilt, shock and loss of self-esteem and altered behavior. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are examples of psychological risks.

-Social/Economic risks: include alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling a subject in a way that will have negative consequences, or in some way diminishing those opportunities and powers a person has by virtue of relationships with others. Economic risks include payment by subjects for procedures not otherwise required, loss of wages or other income and any other financial costs, such as damage to a subject's employability, as a consequence of participation in the research.

-Legal risks: exist when the research methods are such that the subject or others will be liable for a violation of the law, either by revealing that the subject or others have or will engage in conduct for which the subject or others may be criminally or civilly liable, or by requiring activities for which the subject or others may be criminally or civilly liable.